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Friday
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The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1477

RIN 0560–AD04

Disaster Payment Program

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations for the 1990, 1991, and 1992 Disaster Payment Program as authorized by the Food, Agriculture, Conservation, and Trade Act of 1990 (1990 Act), the Dire Emergency Supplemental Appropriations Act of 1992, and the Second Dire Emergency Supplemental Appropriations Act, Fiscal Year 1992.

The regulations are being amended to add new provisions that relate to: Determining the actual production of 1992 corn crop; the application period for allowing producers to file new applications and adjust previously filed applications; and the manner in which disbursement of the funds made available by these acts will be conducted.

EFFECTIVE DATE: April 13, 1993.

FOR FURTHER INFORMATION CONTACT: Diane Sharp, Chief, Production Adjustment Branch, Cotton, Grain, and Rice Price Support Division, Agricultural Stabilization and Conservation Service (ASCS), United States Department of Agriculture (USDA), P.O. Box 2415, Washington, DC 20013–2415, telephone: 202–720–4696.

SUPPLEMENTARY INFORMATION:

Executive Order 12291 and Department Regulation 1512–1

This final rule has been reviewed under USDA procedures established in accordance with provisions of Executive Order 12291 and Departmental Regulation 1512–1 and has been classified as "major" since the program will have an annual effect on the economy exceeding $100 million. A final regulatory impact analysis is available from the above-named individual.

Regulatory Flexibility Act and Environmental Evaluation

It has been determined that the Regulatory Flexibility Act is not applicable to this final rule since the Commodity Credit Corporation (CCC) is not required by 5 U.S.C. 553 or any other provision of the law to publish a notice of proposed rulemaking with respect to the subject matter of this rule. An Environmental Evaluation with respect to the Disaster Payment Program has been completed. It has been determined that this action is not expected to have a significant impact on the quality of the human environment. In addition, it has been determined that this action will not adversely affect environmental factors such as wildlife habitat, water quality, air quality, and land use and appearance. Accordingly, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Federal Assistance Program

The titles and numbers of the Federal assistance programs, as found in the Catalog of Federal Domestic Assistance, to which this rule applies are: Cotton Production Stabilization—10.052; Feed Grain Production Stabilization—10.055; Wheat Production Stabilization—10.058; and Rice Production Stabilization—10.065.

Executive Order 12372

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

Paperwork Reduction Act

The reporting requirements of the current regulations at 7 CFR part 1477 have been approved through June 30, 1993, by the OMB and assigned OMB No. 0560–0050. These reporting requirements will be resubmitted for expedited review under this final rule. No reporting forms were modified. Public reporting burden for these collections is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, room 404–W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project, (OMB No. 0560–0050), Washington, DC 20503.

5 U.S.C. 553

The 1990 Act provides that the regulations necessary for implementation of these programs are to be issued as soon as practicable and without regard to the requirements for notice and public participation in rule making prescribed in 5 U.S.C. 553 or in any directive of the Secretary of Agriculture.

Executive Order 12778

This final rule has been reviewed in accordance with Executive Order 12778. The provisions of this final rule do not preempt State law, and are not retroactive. Before any judicial action may be brought regarding the provisions of this final rule, the administrative appeal remedies at 7 CFR part 780 must be exhausted.

Background

Due to widespread conditions of abnormally cool, wet weather affecting the record 1992 crop of corn, many producers in the Corn Belt States have harvested a crop of unusually low test weight and high moisture. This crop has little economic value. Many producers face an economic emergency due to such low value, and are unable to receive assistance from other existing USDA disaster programs to alleviate the economic emergency and meet 1993 planting needs.

Available evidence indicates the extent of the widespread damage to the 1992 corn crop. Much of the 1992 corn grown in the Corn Belt States has very low net value due to low test weight, foreign material and damaged kernels, and excessive moisture. In many instances, the drying charges and discounts exceed the value of the corn.

The condition of the crop is sometimes so poor that it is virtually worthless for ethanol and other industrial purposes and in some cases contains high levels of naturally occurring toxins. Existing USDA programs are inadequate to meet the immediate cash-flow needs of farmers with low quality 1992 corn who must plant the 1993 corn crop over the next several weeks.

Accordingly, CCC has determined that assistance shall be made available to producers who have such low quality corn. Assistance shall be provided in the manner specified in the 1990 Act, except that CCC shall exclude from actual production of the 1992 crop of corn the quantity of production for which eligible disaster conditions affected the quality of the 1992 crop.

The application period will begin on April 14, and end May 7, 1993. During the application period, producers who have:

(1) Previously filed an application for disaster benefits for the 1992 crop of corn on a farm, may amend that application to include losses due to reduction in the quality of such crop.

(2) Not previously filed applications for disaster benefits for the 1992 crop of corn on a farm, may file applications for losses due to reduction in the quality, provided such producer has not filed for disaster program benefits for both the 1990 and 1991 crop years.

List of Subjects in 7 CFR Part 1477

Agriculture commodities, Disaster assistance, Fraud, Grant programs/agriculture, Reporting and recordkeeping requirements.

Accordingly, 7 CFR part 1477 is amended as follows:

PART 1477—DISASTER PAYMENT PROGRAM FOR 1990 AND SUBSEQUENT CROPS

1. The authority citation for 7 CFR part 1477 continues to read as follows:

Authority: 15 U.S.C. 714b and 714c; Public Law 101–624; Public Law 102–229, 105 Stat. 1701; Public Law 102–368; 106 Stat. 117.

2. Section 1477.20 is redesignated as § 1477.21 and a new § 1477.20 is added to read as follows:

§ 1477.20 Adjustments to program crop production.

Notwithstanding any other provision of this part, the following provisions are applicable to producers of 1992 crop corn whose production has been affected by low quality due to an eligible disaster.

(a) Adjustments will be made to the actual production of 1992 crop corn if the quality of such production has been affected by an eligible disaster. CCC shall adjust the actual production of the 1992 crop of corn by the following factors as determined by CCC to reflect the loss of value in such crop:

(1) Grade #4; production will be reduced by a factor of 20 percent;

(2) Grade #5; production will be reduced by a factor of 50 percent; and

(3) Sample Grade; production will be reduced by a factor of 85 percent.

(b) A request for assistance under this section must be submitted to CCC at the county office in the county where the farm is administratively located by May 7, 1993. Producers who have:

(1) Previously filed an application for disaster benefits for 1992 crop corn on a farm may amend that application to include losses due to reduction in the quality of such crop.

(2) Not previously filed applications for disaster benefits for 1992 crop corn on a farm may file applications for losses due to reduction in the quality, provided such producer has not filed for disaster program benefits for both the 1990 and 1991 crop years.

(c) Any producer entitled to any payment may assign any such payments in accordance with part 1404 of this chapter if the assignment is executed after September 2, 1992.

Signed at Washington, DC, on April 12, 1993.

Bruce R. Weber,

Acting Executive Vice-President, Commodity Credit Corporation.

[FR Doc. 93–8896 Filed 4–13–93; 11:16 am]

BILLING CODE 3410-05-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93–ANE–13; Amendment 39–8525; AD 93–05–22]

Airworthiness Directives; Textron Lycoming Model TIO–540–S1AD Engines

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule, request for comments.

SUMMARY: This amendment adopts a new airworthiness directive (AD) that is applicable to Textron Lycoming Model TIO–540–S1AD engines. This action supersedes priority letter AD 92–12–10 that currently requires inspection, and replacement, if necessary, of the fuel injector fuel lines. This action clarifies when the fuel injector fuel lines should be reinspected. This amendment is prompted by a potential ambiguity concerning when to reinspect the fuel injector fuel lines. The actions specified by this AD are intended to prevent failure of the fuel injector fuel lines allowing fuel to spray into the engine compartment, resulting in an engine fire.

DATES: Effective on May 11, 1993.

Comments for inclusion in the Rules Docket must be received on or before June 15, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), New England Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–ANE–13, 12 New England Executive Park, Burlington, Massachusetts 01803–5299.

FOR FURTHER INFORMATION CONTACT: Nick Minniti, Aerospace Engineer, New York Aircraft Certification Office, ANE–170, FAA, New England Region, 181 South Franklin Avenue, Valley Stream, New York 11581; telephone 516–791–7421; fax 516–791–9024.

SUPPLEMENTARY INFORMATION: On June 5, 1992, the FAA issued priority letter Airworthiness Directive (AD) 92–12–10, applicable to Textron Lycoming Model TIO–540–S1AD engines, which requires inspection, and replacement, if necessary, of the fuel injector fuel lines. That action was prompted by reports of two fatal accidents caused by the failure of fuel injector fuel lines. These fuel injector fuel lines are routed between the fuel manifold and the injector nozzles. Investigation of these accidents revealed that the failed fuel injector fuel lines did not have the required support clamps. This condition, if not corrected, can result in failure of the fuel injector fuel lines allowing fuel to spray into the engine compartment, resulting in an engine fire.

Since the issuance of that priority letter AD, the FAA has identified a potential ambiguity concerning when to reinspect the fuel injector fuel lines as required in paragraph (c) of the compliance section of the priority letter AD. Paragraph (c) of the priority letter AD required a reinspection of the fuel injector fuel lines whenever the fuel injector fuel lines are "disconnected or disturbed." To clarify the intent, the FAA has replaced the word "disturbed" with the words "loosened or moved" in paragraph (c) of this AD.

The FAA has noted a typographical error in the labeling of the paragraphs of the priority letter AD. Paragraph (f) should have been labeled (e), and the following paragraphs should have been labeled (f) and (g). The FAA has

corrected the paragraph labelling accordingly.

Since the unsafe condition described is likely to exist or develop on other engines of the same type design, this AD supersedes priority letter AD 92–12–10 by clarifying when the fuel injector fuel lines should be reinspected.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified under the caption "**ADDRESSES.**" All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 93–ANE–13." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption "**ADDRESSES.**"

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

93–05–22 Textron Lycoming: Amendment 39–8525. Docket 93–ANE–13.

Applicability: Textron Lycoming Model TIO–540–S1AD engines installed on but not limited to Piper PA–32 Series Aircraft (Turbo Saratoga, Turbo Saratoga SP and Turbo Lance II aircraft).

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the fuel injector fuel lines that can result in an engine fire, accomplish the following:

(a) Within 10 hours time in service after the effective date of this AD inspect the fuel injector fuel lines between the fuel manifold and the fuel injector nozzles as follows:

(1) Visually inspect each fuel injector fuel line for missing support clamps or support clamps with a loose, worn or missing support sleeve or cushion. Each fuel injector fuel line must be supported by at least one clamp.

(2) Visually inspect each fuel injector fuel line for evidence of physical damage, including dents and chaffing, and for stains caused by fuel leakage.

(b) Prior to further flight, replace any fuel injector fuel line that does not have a supporting clamp, has a clamp with a loose, worn, or missing support sleeve or cushion, or if the line itself is damaged or has evidence of fuel leakage.

(c) Thereafter, reinspect the fuel lines in accordance with paragraphs (a) (1) and (2) of this AD and replace as necessary any fuel injector fuel lines in accordance with paragraph (b) of this AD at each annual inspection, at each 100-hour inspection, at each engine overhaul, and after any maintenance has been performed on the engine where the fuel injector fuel lines have been disconnected, loosened, or moved.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, New York Aircraft Certification Office. The request should be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, New York Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the New York Aircraft Certification Office.

(e) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(f) This amendment supersedes priority letter AD 92–12–10, issued June 5, 1992.

(g) This amendment becomes effective on May 11, 1993.

Issued in Burlington, Massachusetts, on March 16, 1993.

Jack A. Sain,

Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 93–8890 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 5

Fees for Applications for Contract Market Designation

AGENCY: Commodity Futures Trading Commission.

ACTION: Final schedule of fees.

SUMMARY: The Commission periodically adjusts fees charged for certain program services to assure that they accurately reflect current Commission costs. In this regard, the staff recently reviewed the Commission's actual cost of processing

applications for contract market designation (17 CFR part 5, appendix B). The following fee schedule for FY 1993 reflects the costs to the Commission of providing that service during fiscal years 1990, 1991 and 1992. The fee for applications for contract market designation for futures will be lowered from $15,000 to $11,000, the fee for contract market designation for options will be lowered from $7,000 to $3,000 and, the Commission will continue its incentive for contract markets to simultaneously submit designation applications for futures and options on that future by charging a combined fee of $12,000 (down from $17,000 last year) for both.

EFFECTIVE DATE: April 16, 1993.

FOR FURTHER INFORMATION CONTACT: Gerry Smith, Special Assistant to the Executive Director, Office of the Executive Director, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581, telephone number 202–254–6090.

SUPPLEMENTARY INFORMATION: The Commission periodically reviews the actual costs of providing services for which fees are charged and adjusts its fees accordingly. In connection with its most recent review, the Commission has determined that fees for contract market designations should be adjusted.

I. Computation of Fees

In accordance with the Futures Trading Act of 1982 (7 U.S.C. 16a) the Commission has established fees for certain activities and functions performed by the Commission.[1] In calculating the actual cost of processing applications for contract market designation the Commission takes into account personnel costs, benefits and administrative costs.

The Commission first determines personnel cost by extracting data from the agency's Management Accounting Structured Code (MASC) system. Employees of the Commission record the time spent on each project under the MASC system. The Commission then adds an overhead factor for benefits, including retirement, insurance and leave, based on a government-wide standard established by the Office of Management and Budget in Circular A–76. An overhead factor is also added for general and administrative costs, such as space, equipment and utilities. These general and administrative costs are derived by computing the percentage of Commission appropriations spent on these non-personnel items. The overhead calculations fluctuate slightly due to changes in government-wide benefits and the percentage of Commission appropriations applied to non-personnel costs from year to year. The actual overhead factor for the preceding fiscal year is as follows: FY 1990—98%; FY 1991—94%; FY 1992—99%.

Once the total personnel costs and overhead for each project have been determined, the costs for FY 1990, FY 1991 and FY 1992 are averaged. This results in a calculation of the average annual cost for each project over the three-year period, which is the basis for the fee.

II. Applications for Contract Market Designation

On August 23, 1983 the Commission established a fee for Contract Market Designation. 48 FR 38214. This fee was based upon a three year moving average of the actual costs expended and the number of contracts reviewed in that period of time. The fee charged was reviewed again in FY 1985 and every year after that to determine the fee for the current year. At that time the overwhelming majority of designation applications was for futures contracts as opposed to options contracts. Therefore, the proposed fee covered both futures and options applications. In FY 1992 the Commission reviewed its data on the actual costs for reviewing applications for both futures and options and determined that the cost of reviewing a futures contract was much higher than the cost of reviewing an options contract. It also determined that, when both a futures contract and an option on that futures contract are submitted simultaneously, the cost for review of that options contract is even lower. A review of actual costs of processing applications for contract market designation as a future for FY 1990, FY 1991 and FY 1992 revealed that the average cost over the three year period was $14,555. A review of actual costs of processing applications for contract market designation as an option for FY 1990, FY 1991 and FY 1992 revealed that the average cost over the three year period was $4,640. However, Guideline I was amended on January 22, 1992, and this has resulted in a decline in costs not fully reflected in the three-year average used to calculate fees. Therefore, the Commission has determined, for the current year, to reduce the fee by 25 percent. Accordingly, the fee for applications for contract market designation as a future will be lowered to $11,000. The fee for applications for contract market designation as an option will be lowered to $3,000 in accordance with the Commission's regulations (17 CFR part 5, appendix B). In addition, the combined fee for contract markets submitting designation applications for futures and options on that future simultaneously will be lowered to $12,000.

III. Regulatory Flexibility Act

The Regulatory Flexibility Act ("RFA"), 5 U.S.C. 601 *et seq.*, requires that agencies consider the impact of those rules on small businesses. The fees implemented in this release affect contract markets (also referred to as "exchanges"). The Commission has previously determined that contract markets are not "small entities" for purposes of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, 47 FR 18618 (April 30, 1982). Therefore, the requirements of the Regulatory Flexibility Act do not apply to contract markets. Accordingly, the Chairman, on behalf of the Commission, certifies that the fees implemented herein do not have a significant economic impact on a substantial number of small entities.

Issued in Washington, DC, on April 12, 1993, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 93–8891 Filed 4–15–93; 8:45 am]

BILLING CODE 6351-01-M

[1] For a broader discussion of the history of Commission fees, see 52 F.R. 46070 (Dec. 4, 1987).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket Nos. 87F–0252 and 89F–0496]

Food Additives Permitted for Direct Addition to Food for Human Consumption: Aspartame

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of aspartame as a sweetener and flavor enhancer in hard candy and as a sweetener in soft candy. This action is in response to petitions filed by the NutraSweet Co.

DATES: Effective April 16, 1993; written objections and requests for a hearing by May 17, 1993.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Owen Fields, Center for Food Safety and Applied Nutrition (HFF–333), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9523.

SUPPLEMENTARY INFORMATION: In notices published in the **Federal Register** of August 25, 1987 (52 FR 32059), and December 14, 1989 (54 FR 51325), FDA announced that food additive petitions (FAP's 7A4015 and 0A4185, respectively) had been filed by the NutraSweet Co., 4711 Golf Rd., Skokie, IL 60076 and 1751 Lake Cook Rd., Deerfield, IL 60015, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener and flavor enhancer in hard candies and cough drops (FAP 7A4015) and as a sweetener in soft candy (FAP 0A4185).

No comments were received in response to the filing of FAP 0A4185.

One comment was received in response to the filing of FAP 7A4015. This comment opposed the use of aspartame in hard candies. The comment expressed concern that people, particularly children, with phenylketonuria (PKU) would not be adequately warned about the inclusion of aspartame in hard candies, particularly hard candies that are individually wrapped and labeled.

The agency understands the concern expressed in the comment on FAP 7A4015. However, any hard candy manufactured in compliance with this final rule must also comply with § 172.804(e)(2), which requires that the label of any food containing the additive bear, either on the principal display panel or the information panel, the following statement: "PHENYLKETONURICS: CONTAINS PHENYLALANINE." The agency concludes that this statement provides sufficient notice to phenylketonurics and to parents of young children with phenylketonuria, who will exercise supervision over consumption of hard and soft candies.

The agency notes that aspartame is already approved for use in cough drops under §§ 201.21 and 201.117 (21 CFR 201.21 and 201.117). Therefore, it was not necessary for the agency to evaluate, and the agency did not evaluate, the safety of the use of aspartame for use in cough drops. FDA has evaluated data in the petitions and other relevant material. The agency concludes that the proposed uses of aspartame in hard candies and soft candies are safe, and that the regulations should be amended in § 172.804(c) and (d) as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before May 17, 1993, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 376).

2. Section 172.804 is amended by revising paragraphs (c)(10) and (d) to read as follows:

§ 172.804 Aspartame.

* * * * *

(c) * * *

(10) Breath mints, hard and soft candy.

* * * * *

(d) The additive may be used as a flavor enhancer in chewing gum and hard candy.

* * * * *

Dated: March 25, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–8776 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–01–F

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0, 1, 21 and 74

[FCC 93–110]

Transfer of Certain Application Processing Functions to Gettysburg, PA

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: These rule changes reflect the transfer of certain Common Carrier and Mass Media application processing functions from the Commission's Washington, DC offices to its Gettysburg, Pennsylvania offices. These functions were transferred in order to improve service to the public. The rule changes are intended to apprise the public of the new addresses where certain application files may be found or to which certain applications or other correspondence should be sent.

EFFECTIVE DATE: April 16, 1993.

FOR FURTHER INFORMATION CONTACT: Kent Nakamura, Private Radio Bureau, (202) 632–6940.

SUPPLEMENTARY INFORMATION:

Order

Adopted: February 22, 1993.
Released: March 22, 1993.

By the Commission:

1. The Commission is transferring the processing of certain Mass Media and Common Carrier applications from its Washington, DC offices to the offices of the Private Radio Bureau in Gettysburg, Pennsylvania. By this order, we revise various portions of the Commission's Rules to reflect that transfer. The revisions are attached as appendix A to this order.

2. Because each of these rule changes relates to agency organization, procedure, or practice, the notice and comment and effective date provisions of the Administrative Procedure Act are inapplicable. See 5 U.S.C. 553(b)(A), 553(d).

3. Accordingly, it is ordered that, parts 0, 1, 21, and 74 of the Commission's Rules are amended as set forth below effective upon publication in the **Federal Register**.

List of Subjects

47 CFR Part 0

Freedom of information.

47 CFR Part 1

Administrative practice and procedure.

47 CFR Part 21

Communications common carriers.

47 CFR Part 74

Radio broadcasting, Television broadcasting.

Federal Communications Commission.
William F. Caton,
Acting Secretary.

Rule Changes

Parts 0, 1, 21, and 74 of title 47 of the Code of Federal Regulations are amended as follows:

PART 0—COMMISSION ORGANIZATION

1. The Authority citation for part 0 continues to read as follows:

Authority: Secs. 5, 48 Stat. 1068, as amended; 47 U.S.C. 155.

2. Section 0.453 is amended by revising the introductory text and paragraphs (d), (g) and (l) to read as follows:

§ 0.453 Public reference rooms.

The Commission maintains the following public reference rooms at its offices in Washington, DC and Gettysburg, Pennsylvania. With the exception of the Private Radio Bureau Reference Room, which is located in Gettysburg, Pennsylvania, all reference rooms are located in Washington, DC:

* * * * *

(d) The Mass Media Bureau, Auxiliary Services Reference Room. The following documents, files and records are available for inspection at this location.

(1) International Broadcast applications and related files.

(2) FM Translator applications and related files.

(3) FM Booster station applications and related files.

* * * * *

(g) The Common Carrier Bureau, Domestic Facilities Reference Room. The following documents, files, and records are available for inspection at this location.

(1) Multi-Point Distribution Service application files and related materials.

(2) Space and earth station files and related materials.

(3) Section 214 applications and related files.

* * * * *

(l) The Private Radio Bureau Reference Room. Commercial radio operator application files and all authorizations in the Private Radio Services and files relating thereto, which includes Land Mobile, Microwave, Aviation Ground and Marine Coast applications. All of these materials are available in the Commission's offices in Gettysburg, Pennsylvania. See Section 0.457(f)(3). This reference room also contains station files containing applications and related materials for Remote Pickup, Aural STL/ICR, TV Auxiliary, and Low Power Auxiliary Stations in the Mass Media services. This reference room also contains station files containing applications and related materials for the Point-to-Point Microwave (including the Local Television Transmission Service) and Digital Electronic Message (DEMS) services in the Common Carrier services. Cards summarizing the historical record of applications and dispositions of the Broadcast Auxiliary service through May 1982 are available for inspection as well.

PART 1—PRACTICE AND PROCEDURE

1. The authority citation for part 1 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303; Implement, 5 U.S.C. 552, unless otherwise noted.

2. Section 1.1104 is amended by revising the addresses in the final column of paragraphs 5.a. through c. to read as follows:

§ 1.1104 Schedule of charges for mass media services.

Action	FCC form No.	Fee amount	Fee type code	Address
*	*	*	*	*

5. Auxiliary Services (includes Remote Pickup stations, TV Auxiliary Broadcast stations, Aural Broadcast stations, Aural Broadcast STL and Intercity Relay stations, and Low Power Auxiliary):

Action	FCC form No.	Fee amount	Fee type code	Address
a. Major Action (per application)	.....	.....	.....	Federal Communications Commission, Mass Media Services, P.O. Box 358700, Pittsburgh, PA 15251–5700.

Action	FCC form No.	Fee amount	Fee type code	Address
b. License Renewal (per application)				Federal Communications Commission, Mass Media Services, P.O. Box 358700, Pittsburgh, PA 15251–5700.
c. Special Temporary Authority (other than to remain silent or to extend an existing STA to remain silent).				Federal Communications Commission, Mass Media Services, P.O. Box 358700, Pittsburgh, PA 15251–5700.

* * * * *

3. Section 1.1105 is amended by revising the addresses in the final column of paragraphs 6.a. through g. and 8.a. through g. to read as follows:

§1.1105 Schedule of charges for common carrier services.

Action	FCC form No.	Fee amount	Fee type code	Address

* * * * *

6. Point-to-Point Microwave and Local Television Radio Service:

Action	FCC from No.	Fee amount	Fee type code	Address
a. Conditional License (per station)				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
b. Major Modification of Conditional License or License Authorization (per station).				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
c. Certificate of Completion of Construction (per station).				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
d. Renewal (per licensed station)				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
e. Assignment or Transfer:				
(i) First Station on Application				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
(ii) Each Additional Station				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
f. Extension of Construction Authorization (per station).				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
g. Special Temporary Authority or Request for Waiver of Prior Construction Authorization (per request).				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.

* * * * *

8. Digital Electronic Message Service:

Action	FCC from No.	Fee amount	Fee type code	Address
a. Conditional License (per nodal station)				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
b. Major Modification of Conditional License or License Authorization (per nodal station).				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
c. Certificate of Completion of Construction (per nodal station).				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
d. Renewal (per licensed nodal station)				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
e. Assignment or Transfer:				
(i) First Station on Application				Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.

Action	FCC from No.	Fee amount	Fee type code	Address
(ii) Each Additional Station	.....	.....	.....	Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
f. Extension of Construction Authorization (per station).	.....	.....	.....	Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.
g. Special Temporary Authority or Request for Waiver of Prior Construction Authorization (per request).	.....	.....	.....	Federal Communications Commission, Common Carrier Domestic Radio, P.O. Box 358680, Pittsburgh, PA 15251–5680.

* * * * *

PART 21—DOMESTIC PUBLIC FIXED RADIO SERVICES

1. The authority citation for part 21 continues to read as follows:

Authority: Secs. 1, 2, 4, 201–205, 208, 215, 218, 303, 307, 313, 403, 404, 410, 602; 48 Stat. as amended, 1064, 1066, 1070–1073, 1076, 1077, 1080, 1082, 1083, 1087, 1094, 1098, 1102; 47 U.S.C. 151, 154, 201–205, 208, 215, 218, 303, 307, 313, 314, 403, 404, 602; 47 U.S.C. 552.

2. Section 21.6 is amended by revising paragraphs (b) and (c) to read as follows:

§ 21.6 Filing of applications, fees, and numbers of copies.

* * * * *

(b) Applications requiring fees as set forth at part 1, subpart G of this chapter must be filed in accordance with § 0.401(b) of this chapter. Applications not requiring fees shall be submitted to: Federal Communications Commission, Washington, DC 20554, except that applications in the Digital Electronic Message Service (DEMS) and the Point-to-Point Microwave Service not requiring fees shall be submitted to: Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, PA 17325.

(c) All correspondence or amendments concerning a submitted application shall clearly identify the radio service, the name of the applicant, station location, and the Commission file number (if known) or station call sign of the application involved. All correspondence or amendments concerning a submitted application may be sent directly to the Common Carrier Bureau, with the exception of correspondence or amendments in the DEMS and Point-to-Point Microwave services. In the case of the DEMS and Point-to-Point Microwave services, correspondence or amendments not requiring payment of a fee shall be submitted to: Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, PA 17325.

* * * * *

3. Section 21.13 is amended by adding a new first sentence to paragraph (b) and revising the second sentence in paragraph (b) to read as follows:

§ 21.13 General application requirements.

* * * * *

(b) Applications in the Digital Electronic Message Service (DEMS) and the Point-to-Point Microwave Service shall not cross-reference previously filed material. Applications other than for the DEMS and Point-to-Point Microwave Services may cross-reference previously filed material where documents, exhibits or other lengthy showings already on file with the Commission contain information which is required by an application form and may specifically refer to such information, if:

* * * * *

4. Section 21.303 is amended by revising paragraphs (a), (b), (c), and (d)(1) to read as follows:

§ 21.303 Discontinuance, reduction or impairment of service.

(a) If the public communication service provided by a station in the Domestic Public Radio Services is involuntarily discontinued, reduced or impaired for a period exceeding 48 hours, the station licensee shall promptly give notification thereof in writing to the Commission at Washington, DC 20554. Provided, that in the case of the Point-to-Point Microwave Service, the Local Television Transmission Service, and the Digital Electronic Microwave Service, such notification shall be sent to the Commission at Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325. In every such case, the licensee shall furnish full particulars as to the reasons for such discontinuance, reduction or impairment of service, including a statement as to when normal service is expected to be resumed. When normal service is resumed, prompt notification thereof shall be given in writing to the Commission at Washington, DC 20554 or to the Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325, as appropriate.

(b) No station licensee subject to title II of the Communications Act of 1934, as amended, shall voluntarily discontinue, reduce or impair public communication service to a community or part of a community without obtaining prior authorization from the Commission pursuant to the procedures set forth in part 63 of this chapter or complying with the requirements set forth at § 21.910. In the event that permanent discontinuance of service is authorized by the Commission, the station licensee shall promptly send the station license to the Commission at Washington, DC 20554. Provided, that in the case of the Point-to-Point Microwave Service, the Local Television Transmission Service, and the Digital Electronic Microwave Service, the station license shall be sent to Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 for cancellation. Provided further, that Multipoint Distribution Service station licenses need not be surrendered for cancellation if the discontinuance is a result of a change of status by a Multipoint Distribution Service licensee from common carrier to non-common carrier pursuant to § 21.910.

(c) Any station licensee, not subject to title II of the Communications Act of 1934, as amended, who voluntarily discontinues, reduces or impairs public communication service to a community or a part of a community shall give written notification to the Commission within 7 days thereof. In the event of permanent discontinuance of service, the station licensee shall promptly send the station license to the Commission at Washington, DC 20554. Provided, that in the case of the Point-to-Point Microwave Service, the Local Television Transmission Service, and the Digital Electronic Microwave Service, the

station license shall be sent to Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 for cancellation. Provided further, that Multipoint Distribution Service station licenses need not be surrendered for cancellation if the discontinuance is a result of a change of status by a Multipoint Distribution Service licensee from common carrier to non-common carrier pursuant to § 21.910.

(d) * * *

(1) Submit for cancellation the station license (or licenses) to the Commission at Washington, DC 20554. Provided, that in the case of the Point-to-Point Microwave Service, the Local Television Transmission Service, and the Digital Electronic Microwave Service, the station license(s) shall be sent to Federal Communications Commission, Common Carrier Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 for cancellation.

* * * * *

PART 74—EXPERIMENTAL, AUXILIARY, AND SPECIAL BROADCAST AND OTHER PROGRAM DISTRIBUTIONAL SERVICES

1. The authority citation for part 74 continues to read as follows:

Authority: Secs. 4, 303, 48 Stat. 1066, as amended, 1082, as amended; 47 U.S.C. 154, 303, unless otherwise noted. Interpret or apply secs. 301, 303, 307, 48 Stat. 1081, 1082, as amended, 1083, as amended; 47 U.S.C. 301, 303, 307.

2. Section 74.432 is amended by revising paragraph (k) to read as follows:

§ 74.432 Licensing requirements and procedures.

* * * * *

(k) In the case of permanent discontinuance of operation of a station or system licensed under this subpart, the licensee shall forward the station or system license to the FCC at Federal Communications Commission, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 for cancellation. For purposes of this section, a station which is not operated for a period of one year is considered to have been permanently discontinued.

* * * * *

3. Section 74.433 is amended by revising paragraph (c) to read as follows:

§ 74.433 Temporary authorizations.

* * * * *

(c) An informal request for special temporary authority requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, P.O. Box 358700, Pittsburgh, PA 15251–5700. An informal request for special temporary authority not requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325. All requests must include full particulars including: Licensee's name, call letters of associated broadcast station or stations, name and address of individual designated to receive return authorization, call letters of remote pickup station, if assigned, type and manufacturer of equipment, power output, emission, frequency or frequencies proposed to be used, commencement and termination date, location of operation and purpose for which request is made including any particular justification.

* * * * *

4. Section 74.452 is amended by revising paragraph (c) to read as follows:

§ 74.452 Equipment changes.

* * * * *

(c) The FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 shall be promptly notified of any equipment changes made pursuant to paragraph (b) of this section..

5. Section 74.532 is amended by revising paragraph (f) to read as follows:

§ 74.532 Licensing requirements.

* * * * *

(f) In case of permanent discontinuance of operation of a station licensed under this subpart, the licensee shall forward the station license to the Federal Communications Commission. Broadcast Auxiliary Radio Services. 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 for cancellation

6. Section 74.537 is amended by revising paragraph (c) to read as follows:

§ 74.537 Temporary authorizations.

* * * * *

(c) An informal request for special temporary authority requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, P.O. Box 358700, Pittsburgh, PA 15251–5700. An informal request for special temporary authority not requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services. 1270 Fairfield Road, Gettysburg, Pennsylvania 17325. All requests must include full particulars including: licensee's name, call letters of the associated broadcast station(s), name and address of individual designated to receive the return authorization, call letters of the aural broadcast STL or intercity relay station, if assigned, type and manufacturer of equipment, power output, emission, frequency or frequencies proposed for use, commencement and termination date and location of the proposed operation, and purpose for which request is made including any particular justification.

* * * * *

7. Section 74.551 is amended by revising paragraph (b) to read as follows:

§ 74.551 Equipment changes.

* * * * *

(b) Other equipment changes not specifically referred to in this section may be made at the discretion of the licensee, provided that the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 is promptly notified in writing upon the completion of such changes, and that the changes are described in the notification.

8. Section 74.632 is amended by revising paragraph (g) to read as follows:

§ 74.632 Licensing requirements.

* * * * *

(g) In case of permanent discontinuance of operation of a station licensed under this subpart, the licensee shall forward the station license to the Federal Communications Commission, Broadcast Auxiliary Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325.

9. Section 74.633 is amended by revising paragraph (b) to read as follows:

§ 74.633 Temporary authorizations.

* * * * *

(b) A request for special temporary authority for the operation of a television broadcast auxiliary station may be made by informal application. An informal application for special temporary authority requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, P.O. Box 358700, Pittsburgh, PA 15251–5700. An informal application for special temporary authority not requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325. Such applications shall be filed with the Commission at least 10 days prior to the date of the proposed operation: * * *

10. Section 74.651 is amended by revising paragraph (b) to read as follows:

§ 74.651 Equipment changes.

* * * * *

(b) Other equipment changes not specifically referred to in paragraph (a) of this section may be made at the discretion of the licensee provided that the Federal Communications Commission, Broadcast Auxiliary Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 is promptly notified in writing upon the completion of such changes, and that the changes are described in the notification.

* * * * *

11. Section 74.832 is amended by revising paragraph (1) to read as follows:

§ 74.832 Licensing requirements and procedures.

* * * * *

(i) In case of permanent discontinuance of operation of a station licensed under this subpart, the licensee shall forward the station license to the Federal Communications Commission, Broadcast Auxiliary Radio Services, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325 for cancellation.

* * * * *

12. Section 74.833 is amended by revising paragraph (c) to read as follows:

§ 74.833 Temporary authorizations.

* * * * *

(c) An informal request for special temporary authority requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, Broadcast Auxiliary Radio Services, P.O. Box 358700, Pittsburgh, PA 15251–5700. An informal request for special temporary authority not requiring payment of a fee shall be addressed to the FCC at Federal Communications Commission, 1270 Fairfield Road, Gettysburg, Pennsylvania 17325. All requests must include full particulars including: Applicant's name, statement of eligibility, call letters of associated broadcast station or stations, if any, name and address of individual designated to receive the return telegram, type and manufacturer of equipment, power output, emission, frequency or frequencies proposed to be used, commencement and termination date, location of proposed operation, and purpose for which request is made including any particular justification.

* * * * *

[FR Doc. 93–8758 Filed 4–15–93; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 74–09; Notice 28]

RIN 2127–AE28

Federal Motor Vehicle Safety Standards; Child Restraint Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Final rule.

SUMMARY: This rule amends Federal Motor Vehicle Safety Standard (FMVSS) 213, *Child Restraint Systems*, such that the definition of a built-in child restraint system includes built-in restraints installed in vehicles other than passenger cars. This rule also expands Standard 213's application section so that the standard applies to motor vehicles (equipped with built-in restraints), as well as to child restraints by themselves. In response to a petition for rulemaking from Ford Motor Company, this rule also amends Standard 213's labeling and informational requirements for built-in restraints. The effect of these changes is to apply the standard's dynamic performance requirements for built-in restraints to a greater number of restraint systems, simplify the labeling requirements, and better ensure that built-in systems intended for used vehicles are properly installed in those vehicles.

DATES: The amendment is effective on October 13, 1993.

Petitions for reconsideration of the final rule must be received by May 17, 1993.

ADDRESSES: Petitions for reconsideration should refer to the docket number and notice number of the notice and be submitted to: Administrator, room 5220, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mr. Charles Hott, NHTSA Office of Vehicle Safety Standards, room 5320C, 400 Seventh Street SW., Washington, DC 20590 (202–366–0247).

SUPPLEMENTARY INFORMATION: On January 9, 1992 (57 FR 870), NHTSA published a notice of proposed rulemaking (NPRM) concerning several of the requirements in Standard 213, *Child Restraint Systems*, for built-in child restraint systems. The standard defines a built-in child restraint system as "any child restraint system that is an integral part of a passenger car" (S4). The notice proposed amending the definition to include systems installed in vehicles other than passenger cars. The notice also proposed amending Standard 213's application section so that the standard applies to motor vehicles (that have built-in restraints), as well as to child restraints by themselves. Further, the notice proposed amendments concerning the manner in which manufacturers label and instruct consumers to use built-in restraints. The reasons for the proposals were fully discussed in the NPRM.

NHTSA received comments on the NPRM from Chrysler Corporation, General Motors Corporation, Advocates for Highway and Auto Safety (Advocates), Insurance Institute for Highway Safety, National Transportation Safety Board, National Automobile Dealers Association, Ford Motor Company, Center for Auto Safety (CAS), and Hassel Free, Inc., a manufacturer of built-in systems. The commenters unanimously supported the proposals to amend the application of the standard. All commenters, except for Advocates and CAS, supported the proposals to amend the informational requirements.

Today's rule adopts the proposed amendments, with slight revisions. The definition of "factory-installed built-in restraint" is changed to include restraints installed by alterers and final-stage manufacturers. The labeling requirement is changed to provide that a certification label need not be affixed to a factory-installed built-in restraint. The requirement that built-in systems must include manufacturing instructions excludes systems installed in a vehicle or designed for a specific vehicle model and seating position. These and other amendments are discussed below.

I. Amending the Application of Standard 213

a. Applying 213 to Motor Vehicles

This rule amends S3, *Application*, of Standard 213 to convert the standard from an equipment standard into both a vehicle standard and an equipment standard. S3 is amended to read, "This standard applies to passenger cars, multipurpose passenger vehicles, trucks and buses, and to child restraint systems for use in motor vehicles and aircraft." This change makes the vehicle manufacturer responsible for certifying compliance with Standard 213 with respect to built-in restraints.

NHTSA disagrees with Advocates' comment that the first part of S3 should state that the standard applies to "motor

vehicles" instead of specifying only certain types of vehicles. Specifying the particular types of vehicles to which the standard applies is consistent with the application section of all of the other FMVSS's that apply to vehicles. Further, vehicles not specified in S3, such as motorcycles and trailers, are unlikely to be manufactured with built-in child restraint systems. In any event, a child restraint installed on a vehicle not listed in S3 is a "built-in child restraint system" under Standard 213. The vehicle need not be listed in S3 for the manufacturer to be responsible under 49 CFR part 579, Defect and Noncompliance Responsibility, for recalling the vehicle if the restraint does not comply with Standard 213 or contains a safety-related defect.

b. Applying 213's Dynamic Test Requirements to More Systems

This rule adopts the proposed amendment to the definition of "built-in child restraint system." "Built-in child restraint system" will be defined as a child restraint system that is designed to be an integral part of and permanently installed in a motor vehicle. As a result of this amendment, child restraints newly included in the definition must meet Standard 213's dynamic performance requirements for built-in systems.

Advocates is incorrect that this amendment requires add-on restraints that are permanently installed in a used vehicle to be certified as meeting the requirements for "built-in" systems. Since an add-on restraint is not designed to be an integral part of a vehicle, it does not satisfy the definition of built-in restraint and its manufacturer is not responsible for certifying it as such. Also NHTSA does not agree with Advocates that all restraints installed in used vehicles should be considered built-in restraints. Persons installing used equipment in used vehicles do not have the responsibility under the National Traffic and Motor Vehicle Safety Act to certify the compliance of the equipment or vehicle with the FMVSS's.

c. Defining Factory-Installed Built-In Systems

This rules amends the definition of "factory-installed built-in child restraint system." A factory-installed built-in system is currently defined as a built-in system that was installed in a motor vehicle at the time of the vehicle's delivery to a dealer or distributor for distribution. Today's amendment includes restraints installed by alterers and final-stage manufacturers in the definition.

The National Automobile Dealers Association (NADA) and Hassel Free, Inc. suggested the change in their comments. These commenters suggested that since alterers and final-stage manufacturers are subject to the same recall responsibilities as single-stage manufacturers, they take the same precautions as single-stage manufacturers to trace a defective or noncomplying item of equipment installed on the vehicle. For example, similar to the procedure used by a single-stage manufacturer, an alterer or final-stage manufacturer records the vehicle identification number (VIN) of the vehicles into which they install built-in restraints. Those precautions enable the alterer or final-stage manufacturer to identify which of its vehicles contain a defective or noncomplying restraint, and trace the owners of those vehicles to provide notice of a recall campaign.

NHTSA agrees that alterers and final-stage manufacturers should be subject to the same labeling requirements as single-stage manufacturers. The means that can be used to notify owners of a defect in the restraint or a failure to comply with FMVSS 213 are the same for all three types of manufacturers. Accordingly, the definition of a factory-installed built-in child restraint is amended as follows:

A factory-installed built-in child restraint is a built-in restraint that has been or will be permanently installed in a motor vehicle before that vehicle is certified as a completed or altered vehicle in accordance with part 567 of this chapter.

II. Amending the Informational Requirements of Standard 213

a. Labeling Built-In Systems (Ford Petition)

This rule removes the requirement in S5.5.4 that a factory-installed system must be labeled with the information specified in S5.5.5 (a) through (d), i.e., with the restraint's model name or number, the manufacturer's name, and the date and place of manufacture. In response to Ford's comment, the requirement of S5.5.5(e) is also removed. That paragraph requires that the restraint must be labeled with a certification of conformance to the FMVSS's. Ford pointed out that S5.5.5(e) is redundant for factory-installed built-in restraints since certification to Standard 213 would be provided through the vehicle certification label. Ford is correct that the vehicle's certification would include certification to Standard 213.

Advocates and CAS objected to the proposed amendment. These commenters believed there could be situations where an owner of a factory-installed built-in restraint would need the labeling of S5.5.5 (a) through (d) to identify the restraint. Advocates believed the vehicle owner might seek to have a damaged factory-installed built-in restraint replaced by a motor vehicle repair shop. "Without knowledge of the name of the restraint manufacturer, or the model name or number of the particular restraint built-in to the vehicle, replacement with an inadequate or inappropriate child restraint may result." (Advocates' comment, p. 6.) CAS believed the labeling is needed in case the built-in restraint is removed from a vehicle and installed in another. CAS also believed the labeling is "a convenient and inexpensive way to double-check whether a given factory-installed built-in restraint is subject to recall." (CAS comment, pp. 2–3.)

The agency does not believe the reasons provided by Advocates and CAS warrant a requirement for the labeling. An owner wishing to replace a damaged factory-installed restraint with an identical restraint can obtain information on the replacement seat from the vehicle manufacturer. Also, NHTSA does not agree with CAS that switching a factory-installed restraint between vehicles will occur with any regularity to warrant the restraint labeling. Also, there is no information supporting the view that vehicle owners are not being properly informed of vehicle recalls, and that there is a need for a means to enable owners to double check recall information.

b. Consumer Instructions

This rule adopts the proposed changes to the standard's requirements for printed consumer instructions. Advocates and CAS objected to removing the requirement that factory-installed built-in restraints have a storage location for the instructions. Advocates wanted NHTSA to require the storage location, and require manufacturers to provide an instruction booklet. (Instructions on using the factory-installed built-in restraints are required to be placed in the vehicle owner's manual (5.6.2).) Advocates believed an additional instruction booklet stored on the restraint would be more convenient for and familiar to consumers than the vehicle owner's manual. The commenter said the greater convenience and familiarity would increase the likelihood of consumers referring to the instructions and correctly using the restraint. CAS

wanted instructions to be printed on each restraint.

NHTSA has decided not to require the separate booklet of instructions for factory-installed restraints. NHTSA did not specifically propose such a requirement and did not receive comment on it apart from the suggestion by Advocates. More important, had the agency received significant comment on the idea, NHTSA would not have adopted it. The vehicle owner's manual is the source of information about the vehicle's various safety systems and designs. It is logical, therefore, that information about the child restraint would be located in that manual. Consumers are familiar with the owner's manual, know that they should refer to the manual for detailed information about using the systems and equipment on the vehicle, and know where to find the manual. It is reasonable to assume consumers will use the manual for information about the child restraint, just as they do for adult restraints and other safety equipment. NHTSA is not aware of a safety need to supplement the manual's instructions for built-in systems with a separate information booklet.

NHTSA also concludes this rule should not require built-in restraints to be labeled with detailed instructions, as CAS suggested. The agency has no information that suggests a need for the requirement. There is also no information on the detail that should be required for the instructions, the availability of space on restraint labels, and the cost and burdens of the labeling.

CAS objected to removing S5.6.4 without requiring a new label for built-in beds. S5.6.4 states that built-in restraints should have an instruction that explains that the bed should be positioned so that the child's head is near the vehicle's center (i.e., mid-way between the sides of the car). CAS asked NHTSA to require built-in beds to be labeled with a consumer instruction to place the child's head near the vehicle's center.

NHTSA has decided not to require the suggested labeling. Car beds typically have a three-point harness system whose configuration indicates to the consumer where the baby's head should be placed. Also, there is no comparable labeling requirement for add-on child beds. The need for the labeling for built-in beds is therefore undemonstrated. In addition, Standard 213 already requires manufacturers to include instructions on positioning a child in a built-in bed, in the printed material accompanying each bed. In response to CAS, however, NHTSA will expressly provide in S5.6.2 that the instructions for each car bed shall explain that the child should be positioned in the bed in such a way that the child's head is near the center of the vehicle. NHTSA will also specify in S5.6.3 that the installation instructions for built-in car beds shall explain that the bed should be installed so that the child's head will be near the center of the vehicle.

c. Installation Instructions

This rule adopts a requirement that built-in restraints must have instructions for installing the system in a motor vehicle, but excludes certain systems from the requirement. The excluded systems are built-in restraints that have been installed, and factory-installed built-in systems that have not yet been installed but are designed for a specific vehicle model and seating position. Restraints that have been installed in a vehicle are excluded because instructions are not needed after the manufacturing process is completed. The latter exclusion responds to Ford's comment. Factory-installed restraints that are designed for a specific vehicle model and seating position are excluded because the particular configuration of the vehicle interior has already been accounted for in the design of the restraint.

CAS suggested further labeling and disclosure requirements regarding the installation instructions for aftermarket built-in restraints (i.e., built-in restraints other than factory-installed ones). CAS believed these restraints are not permanent fixtures of the vehicle and that they can be used over and over again in different vehicles. CAS said that the restraint manufacturer should disclose to the consumer all the unsuitable applications there may be for the restraint (e.g., that the restraint is incompatible with a particular type of minivan design), and that the disclosures should be on the packaging for the restraint, in the user instructions, and permanently labeled on the restraint.

NHTSA does not agree that these requirements are necessary. Aftermarket built-in restraints are designed to be permanently installed in the vehicle, and typically only fit into a particular type and model of vehicle because of the variation between vehicle designs. Since it is unlikely that such a restraint will be re-installed in another vehicle after its first installation, it doe not appear necessary to disclose unsuitable applications after the child restraint has been installed.

III. Other Amendments

a. Definition of Specific Vehicle Shell

This rule amends the definition of "specific vehicle shell" in S4 of Standard 213. This rule adopts the slight revisions to the definition that the agency had proposed to make the definition more appropriate for testing aftermarket built-in systems than the present definition. Hassel Free suggested making slight revisions for the same purpose. Hassel Free stated that the definition might be confusing because it refers to "front seat" and "rear seat" as though the vehicle for the built-in restraint has only front and rear seats. The commenter suggested changing the definition to reflect the fact that vehicles such as vans can have a row of seats between the front and rear seats. The commenter said such a change would be consistent with the Canadian test procedures for built-in restraints. NHTSA agrees, and has made the changes in this rule.

b. Conforming Amendments

This rule slightly revises S6.1.2.1.1(b) and 6.1.2.1.2(b), part of the test procedures for built-in child restraints. Those sections direct that the restraint is to be tested by activating the restraint in the specific vehicle shell or the specific vehicle in accordance with the manufacturer's instructions provided "in the vehicle owner's manual." Since the instructions for aftermarket restraints are not in the vehicle owner's manual, reference to the manual has been removed in 6.1.2.1.1(b) and 6.1.2.1.2(b).

This final rule does not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (Safety Act; 15 U.S.C. 1392(d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. Section 105 of the Safety Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has examined the impact of this rulemaking action and determined that it is not major within the meaning of Executive Order 12291 or significant within the meaning of the Department of Transportation's regulatory policies and procedures. NHTSA has further determined that the effects of this rulemaking are so minor that preparation of a final regulatory evaluation is not warranted. NHTSA believes that manufacturers will be minimally affected by today's amendment to the definition of a built-in child restraint system. Based on available information, manufacturers of restraints that are newly included in the definition now design their product to meet Standard 213 requirements for "built-in" systems. Vehicle manufacturers will be minimally affected by today's amendment to Standard 213's application section, because they are already responsible under 49 CFR part 579, Defect and Noncompliance Responsibility, for recalling the vehicle in the event the restraint it installed does not comply with Standard 213 or contains a safety-related defect. NHTSA also believes that manufacturers will be minimally affected by the amendment to the labeling requirements. The amendment would affect some but not all of the information that is required to be labeled on or provided with the restraint.

Regulatory Flexibility Act

NHTSA has considered the effects of this rulemaking action under the Regulatory Flexibility Act. I hereby certify that it will not have a significant economic impact on a substantial number of small entities. To our knowledge there are only a few manufacturers of built-in systems that are small businesses. Regardless of the number of small entities, NHTSA believes the economic impact on them is not significant, since manufacturers producing systems that are newly included in the "built-in restraint" definition are now designing their product to meet Standard 213's dynamic requirements for built-in-systems. The labeling amendments will minimally affect these manufacturers, since this rule changes only some but not all of the information that is required to be labeled on or provided with a restraint. Alterers and final-stage manufacturers will be minimally affected by today's amendment to the definition of "factory-installed built-in child restraint system." The amendment has the effect of excluding built-in restraints installed by these manufacturers from only some of Standard 213's labeling requirements. The bulk of the standard's labeling requirements continue to apply.

Executive Order 12612

This rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and the agency has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environmental Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—[AMENDED]

In consideration of the foregoing, NHTSA amends 49 CFR part 571 as set forth below.

1. The authority citation for part 571 continues to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.213 [Amended]

2. In § 571.213, S3 is revised to read as follows:

S3. *Application.* This standard applies to passenger cars, multipurpose passenger vehicles, trucks and buses, and to child restraint systems for use in motor vehicles and aircraft.

3. In § 571.213, S4 is amended by revising the definitions of "built-in child restraint system," "factory-installed built-in child restraint system," and "specific vehicle shell" to read as follows:

S4. *Definitions.*

* * * * *

Built-in child restraint system means a child restraint system that is designed to be an integral part of and permanently installed in a motor vehicle.

* * * * *

Factory-installed built-in child restraint system means a built-in child restraint system that has been or will be permanently installed in a motor vehicle before that vehicle is certified as a completed or altered vehicle in accordance with part 567 of this chapter.

* * * * *

Specific vehicle shell means the actual vehicle model part into which the built-in child restraint system is or is intended to be fabricated, including the complete surroundings of the built-in system. If the built-in child restraint system is or is intended to be fabricated as part of any seat other than a front seat, these surroundings include the back of the seat in front, the interior rear side door panels and trim, the floor pan, adjacent pillars (e.g., the B and C pillars), and the ceiling. If the built-in system is or is intended to be fabricated as part of the front seat, these surroundings include the dashboard, the steering mechanism and its associated trim hardware, any levers and knobs installed on the floor or on a console, the interior front side door panels and trim, the front seat, the floor pan, the A pillars and the ceiling.

* * * * *

4. In § 571.213, the introductory text of S5 is revised to read as follows:

S5. *Requirements for motor vehicles with built-in child restraint systems and for child restraint systems manufactured for use in motor vehicles.* Each motor vehicle with a built-in child restraint system shall meet the requirements in this section when, as specified, tested in accordance with S6.1 and this paragraph. Each child restraint system manufactured for use in motor vehicles shall meet the requirements in this section when, as specified, tested in accordance with S6.1 and this paragraph. Each add-on system shall meet the requirements at each of the restraint's seat back angle adjustment positions and restraint belt routing positions, when the restraint is oriented in the direction recommended by the manufacturer (e.g., forward, rearward or laterally) pursuant to S5.6, and tested with the test dummy specified in S7.

* * * * *

5. In § 571.213, (introductory text) and S5.1.3.1(a) are republished and S5.1.3.1(b) is revised to read as follows:

S5.1.3.1 *Child restraint systems other than rear-facing ones and car beds.* Each child restraint system, other than a rear-facing child restraint system or a car bed, shall retain the test dummy's torso within the system.

(a) In the case of an add-on child restraint system, no portion of the test dummy's head shall pass through a vertical transverse plane that is 32 inches forward of point z on the standard seat assembly, measured along the center SORL (as illustrated in figure 1B), and neither knee pivot point shall

pass through a vertical, transverse plane that is 36 inches forward of point z on the standard seat assembly, measured along the center SORL.

(b) In the case of a built-in child restraint system, neither knee pivot shall pass through a vertical, transverse plane that is 36 inches forward of the hinge point of the specific vehicle seat into which the system is or is intended to be built, measured along a horizontal line parallel to the vehicle's longitudinal center line and the center line of the vehicle seat.

* * * * *

6. In § 571.213, S5.2.1.2 (introductory text) and S5.2.1.2(a) are republished and S5.2.1.2(b) is revised to read as follows:

S5.2.1.2 A front-facing child restraint system is not required to comply with S5.2.1.1 if the target point on either side of the dummy's head is below a horizontal plane tangent to the top of—

(a) The standard seat assembly, in the case of an add-on child restraint system, when the dummy is positioned in the system and the system is installed on the assembly in accordance with S6.1.2.

(b) The vehicle seat, in the case of a built-in child restraint system, when the system is activated and the dummy is positioned in the system in accordance with S6.1.2.

7. In § 571.213, S5.2.2.2(a) is revised to read as follows:

S5.2.2.2 Each forward-facing child restraint system shall have no fixed or movable surface—

(a) * * *

(2) Parallel to a vertical plane through the longitudinal center line of the vehicle seat, in the case of a built-in child restraint system, and,

* * * * *

8. In § 571.213, S5.5.4 and the introductory text of S5.5.5 are revised to read as follows:

S5.5.4(a) Each built-in child restraint system other than a factory-installed built-in restraint shall be permanently labeled with the information specified in S5.5.5 (a) through (k). The information specified in S5.5.5 (a) through (j) shall be visible when the system is activated for use.

(b) Each factory-installed built-in child restraint shall be permanently labeled with the information specified in S5.5.5 (f) through (j), so that the information is visible when the restrain is activated for use. The information shall also be included in the vehicle owner's manual.

S5.5.5 The information specified in paragraphs (a) through (k) of this section that is required by S5.5.4 shall be in English and lettered in letters and numbers that are not smaller than 10-point type and are on a contrasting background.

* * * * *

9. In § 571.213, S5.6.2 is revised, S5.6.2.1 and S5.6.2.2 are republished, and S5.6.2.3 is added to read as follows:

S5.6.2 *Built-in child restraint systems.* (a) Each built-in child restraint system shall be accompanied by printed instructions in English that provide a step-by-step procedure, including diagrams, for activating the restraint system, positioning a child in the system, adjusting the restraint and, if provided, the restraint harness to fit the child. The instructions for each built-in car bed shall explain that the child should be positioned in the bed in such a way that the child's head is near the center of the vehicle.

(b) Each motor vehicle equipped with a factory-installed built-in child restraint shall have the information specified in paragraph (a) of this section included in its vehicle owner's manual.

S5.6.2.1 The instructions shall explain the primary consequences of not following the manufacturer's warnings for proper use of the child restraint system in accordance with S5.5.5 (f) through (i).

S5.6.2.2 The instructions for each built-in child restraint system other than a factory-installed restraint, shall include the following statement, inserting an address and telephone number: "Child restraints could be recalled for safety reasons. You must register this restraint to be reached in a recall. Send your name, address and the restraint's model number and manufacturing date to (*insert address*) or call (*insert telephone number*). For recall information, call the U.S. Government's Auto Safety Hotline at 1–800–424–9393 (202–366–0123 in DC area)."

S5.6.2.3. Each built-in child restraint system other than a factory-installed built-in restraint, shall have a location on the restraint for storing the instructions.

10. In § 571.213, S5.6.3 is revised to read as follows:

S5.6.3 Each built-in child restraint system, other than a system that has been installed in a vehicle or a factory-installed built-in system that is designed for a specific vehicle model and seating position, shall be accompanied by instructions in English that provide a step-by-step procedure for installing the system in a motor vehicle. The instructions shall specify the types of vehicles and the seating positions into which the restraint can or cannot be installed. The instructions for each car bed shall explain that the bed should be installed so that the child's head will be near the center of the vehicle.

11. In § 571.213, S5.6.4 through S5.6.6 are removed.

12. In § 571.213, S6.1.2.1.1(b) is revised to read as follows:

S6.1.2.1.1 *Test configuration I.*

(a) * * *

(b) In the case of each built-in child restraint system, activate the restraint in the specific vehicle shell or the specific vehicle, in accordance with the manufacturer's instructions provided in accordance with S5.6.2.

13. In § 571.213, S6.1.2.1.2(b) is revised to read as follows:

S6.1.2.1.2. *Test configuration II.*

(a) * * *

(b) In the case of each built-in child restraint system which is equipped with a fixed or movable surface described in S5.2.2.2, or a built-in booster seat with a top anchorage strap, activate the system in the specific vehicle shell or the specific vehicle in accordance with the manufacturer's instructions provided in accordance with S5.6.2.

* * * * *

Issued on April 8, 1993.

Howard M. Smolkin,

Executive Director.

[FR Doc. 93–8793 Filed 4–15–93; 8:45 am]

BILLING CODE 4910-59-M

Proposed Rules

Federal Register
Vol. 58, No. 72
Friday, April 16, 1993

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 317

[Docket No. 86-049W]

RIN 0583-AA71

Labeling of Meat Food Products, Under Certain Circumstances, that Contain Mechanically Separated (Species)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is withdrawing its proposal of September 9, 1988, to amend the Federal meat inspection regulations by excepting, under certain circumstances, meat food products that contain Mechanically Separated (Species) (MS(S)) as an ingredient from the requirement that the labels of meat food products include a list of the common or usual names of all ingredients used, which would include the ingredient MS(S). This action is being taken as a result of a thorough and careful review undertaken by FSIS of the rulemaking record of the proposed rule.

EFFECTIVE DATE: April 16, 1993.

FOR FURTHER INFORMATION CONTACT: Margaret O'K. Glavin, Deputy Administrator, Regulatory Programs, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 720-2709.

SUPPLEMENTARY INFORMATION: On April 27, 1976, a notice of proposed rulemaking was published that included, among other things, a proposal for permitting the manufacture of three types of products resulting from the mechanical separation and removal of most of the bone from attached skeletal muscle tissue (41 FR 17560). Also on April 27, 1976, an interim rule was published that included standards for the use of "Mechanically Deboned Meat" (MDM) (41 FR 17535). The interim regulation provided that Mechanically Deboned Meat could be identified on the labeling of products in which it was permitted to be used by its species name; e.g., beef or pork.

The interim regulation was challenged by a coalition of various consumer-oriented public interest groups. State officials, and a member of Congress in *Community Nutrition Institute* v. *Butz (CNI* v. *Butz*, 420 F. Supp. 751 (D.D.C. 1976). The Court in *CNI* v. *Butz* held in ruling on a motion for preliminary injunction, among other things, that, in its opinion, MDM was not meat as traditionally defined because of its bone particle content. The Court concluded that these bone particles must be regarded as having been added to meat during mechanical processing of MDM, and, in the case of a finished processed product to which MDM has been added, as a substance added to the product. It also appeared to the Court that the interim regulation, which did not require MDM to be declared on the label, permitted misbranding of a product that contained MDM since the calcium content of such a product would be higher than that of a comparable product prepared without MDM. The Court stated that, since the public expects the "usual product," it would be misled by the labeling permitted by the regulation. The Court felt that this could prove especially harmful to persons on calcium-restricted diets, who would be misled into thinking that the product contained no more than the usual amount of calcium. The Court also raised certain health and safety questions about MDM. The Court issued an injunction enjoining the Secretary from giving further effect to the interim regulation with respect to MDM.

In order to respond to the health and safety questions raised by the Court, the Department initiated an analytical program to develop data on the amounts of nutrients and substances of concern which might be present in MDM. A panel was assigned to undertake this evaluation. As a result of the panel's conclusions and recommendations, *CNI* v. *Butz*, and the widespread public interest and concern about MDM, a revised proposal was published on October 6, 1977.

The proposal provided, among other things, that the product be named "Tissue from Ground Bone" (TFGB); that the product be labeled "Tissue from Ground (Species) Bone" in the ingredients statement of a meat food product in which it is used; that the name of the meat food product in which it is used be qualified by the term "Tissue from Ground Bone Added"; and that the product be classified as a meat food product rather than as a class of meat (42 FR 54437).

As a result of the rulemaking proceeding, the Administrator concluded in the final rulemaking document published in 1978 (43 FR 26416) that, among other things, the product should be named "Mechanically Processed (Species) Product" or MP(S)P. The Administrator also concluded that a qualifying statement should be added to finished product names to indicate the presence of MP(S)P, since MP(S)P is unique and would not be an expected ingredient; that finished product names should bear the additional qualifying statement, "Contains Up to _____% Powdered Bone" because the need of some individuals to limit their intake of calcium is an important consideration; and that MP(S)P should be listed separately from "meat" in its order of predominance by weight in the ingredients statement of finished products because MP(S)P is not meat and it would be a standardized product following publication of the rule.

After these regulations became effective, members of the red meat industry contended that not much of this product was used. They further contended that the failure to market products containing MP(S)P was due to regulatory requirements which they believed went beyond what was necessary to protect the public, and they asked the Department to reconsider these requirements.

Following additional reviews and analyses, the Department issued a proposed rule on July 31, 1981 (46 FR 39274). The rulemaking document indicated that, among other things, the Department continued to believe that mechanically processed product differed materially from "meat" in its composition and consistency and that the characteristics, production, and use of this product should be subject to regulatory definition and standardization. Therefore, the Department indicated that it believed that this product should be listed separately in the ingredients statement

of a meat food product in which it is used, in accordance with the general labeling requirements for meat food products, and in light of consumers' interest in knowing each of the ingredients in the foods that they purchase.

Based on comments received and further evaluation of relevant information, in 1982 the Department promulgated a final rule which amended the Federal meat inspection regulations by, among other things, modifying the definition and standard for the product, and the labeling requirements for such product and meat food products in which it may be used (47 FR 28214). The name of the product was changed from "Mechanically Processed (Species) Product" to "Mechanically Separated (Species)" (MS(S)) to provide a more meaningful and concise description of its characteristics. A labeling requirement for the product was established to ensure that the product was used in accordance with regulatory requirements. The requirement that the names of meat food products be qualified to indicate the presence of this product as an ingredient was deleted as unnecessary. Further, the requirement that the names of meat food products be further qualified to indicate the percentage of powdered bone they contained was replaced by a requirement that their labels declare, in certain circumstances, calcium content either as part of nutrition labeling information or, if the meat food product did not bear nutrition labeling, in a prominent statement in immediate conjunction with the ingredients list. The Department noted that the requirement of calcium content labeling, under the circumstances set forth in the rule, was designed to meet the needs of a limited population as opposed to the general population. The calcium content labeling requirement was designed to assure that persons on calcium-restricted diets had adequate information, while not misinforming the general population. The Department concluded that the calcium content approach was preferable to indicating the percentage of powdered bone because it would respond to the needs of calcium-sensitive individuals without having unwarranted, negative effects on the general population's evaluation of meat food products containing MS(S).

A definition and standard of identity for this product was retained since, as the Department noted in its proposal and final rulemaking documents, the consistency of this product and its content of bone, bone marrow, and certain minerals, as well as muscle tissue are materially different from those of meat. The requirement that the name of the product be listed in its proper order of predominance in the ingredients statement on the label of a meat food product in which it is used, consistent with the general requirements for declaring ingredients in meat food products, was also retained. The product's distinctive character and separate regulatory standard were the basis for the ingredient declaration requirement, and not the product's wholesomeness or fitness for consumption or the level of particular meat food product in which it would be included as an ingredient.

The final 1982 regulations were challenged in *Community Nutrition Institute, et al.* v. *Block, et al.*, Civil Case No. 82–2009 (D.D.C. decided Dec. 1, 1982). The plaintiffs challenged the amended regulations contending, among other things, that they permitted the sale of misbranded meat food products because of the product name change to MS(S) and the elimination from the labeling of meat food products, in which MS(S) may be used, of the statements that qualified the name of the meat food product by indicating the presence of MS(S) and the percentage of powdered bone. The plaintiffs contended that the labeling required by the amended regulations, i.e., listing of MS(S) in the ingredients statement and the calcium declaration under certain circumstances, was insufficient under the Federal Meat Inspection Act. The United States District Court upheld the regulations, and the plaintiffs appealed. The United States Court of Appeals for the District of Columbia upheld the regulations in *Community Nutrition Institute, et al.* v. *Block, et al.*, 749 F.2d 50 (D.C. Cir. 1984).

On September 9, 1988, FSIS published a proposed rule (53 FR 35089) to further amend the labeling requirements, under certain circumstances, for meat food products that contain MS(S). It was proposed that if MS(S) comprises no more than 10 percent of the livestock and poultry product portion of a meat food product, and if the calcium content of the meat food product, irrespective of amount, is stated on the product label in a certain manner, MS(S) would be allowed to be designated in the ingredients statement as the species of livestock from which it is derived; e.g., "pork," rather than "mechanically separated pork." The proposal was in response to a petition received on behalf of Bob Evans Farms, Inc., Columbus, Ohio; Odom Sausage Company, Madison, Tennessee; Sara Lee Corporation, Memphis, Tennessee; and Owens Country Sausage, Inc., Richardson, Texas (see Notice of Petition for Rulemaking at 52 FR 10766, April 3, 1987). FSIS had settled a lawsuit, *Bob Evans Farms, Inc., et al.* v. *Lyng, et al.*, Civil Action No. 86–1687 (D.D.C. filed June 17, 1986), brought by those petitioners, by committing to give expeditious consideration to a petition to be submitted by the petitioners to amend the existing labeling regulations for MS(S). The central premise of the petitioners' arguments is that when MS(S) is used at a 10 percent or less level of the meat and poultry product portion of a meat food product, calcium content labeling information, as opposed to a separate identification of MS(S) in the ingredients statement of the product, is all that is needed to ensure that the labeling of the meat food product is not false or misleading. The Department published the proposal to obtain comments and data on this issue.

FSIS received 5,084 comments in response to the proposal. Of the 5,084 comments, 3,270, or approximately 64 percent, opposed the proposal, and 1,814, or 36 percent, favored the proposal. The following is a summary of the comments and the major issues raised.

Of the 36 percent of the comments favoring the proposal, approximately 90 percent were from private citizens. These comments stated that products containing no more than 10 percent MS(S) would be more informatively labeled with an ingredients statement listing for calcium content than with the term "mechanically separated beef." It was asserted that calcium content is relevant information about the finished products, whereas the term "MS(S)" describes the way in which that small constituent part of the product was processed.

Other comments favoring the proposal, largely from the meat industry and associations representing the meat industry, stated that disclosing the calcium content of a finished product is a labeling method superior to simply listing MS(S) as an ingredient since, they contend, calcium content represents the only significant difference between products containing MS(S) and those that do not. These commenters also stated that labeling which contains the term "mechanically separated" is largely irrelevant because it refers only to a processing procedure rather than to any intrinsic feature of this type of meat. Some industry comments, noting that there are not regulations governing comparable mechanically separated poultry products, stated that because mechanically separated poultry is used without restriction, the Agency's

regulatory policies are inconsistent and inequitable.

Approximately 64 percent of the comments opposed the proposal. The majority of these comments were from private citizens, with a few opposing comments from members of industry. These comments contend that if mechanically separated product is used, it should be listed in the ingredients statement just like any other ingredient in the finished product. Most comments opposing the proposal focused on consumers' right to know when ingredients such as MS(S) are present in food. Some comments stated that the petitioners' own assertion that consumers are reluctant to purchase products labeled as containing MS(S) indicates consumers want that information and is itself justification for requiring it to be listed as MS(S) in the ingredients statement. Some commenters stated that if the name MS(S) really constitutes a marketing problem for its manufacturers, then the manufacturers should bear the burden of educating the consumer about its benefits, rather than attempting to hide its presence.

The Department has carefully and thoroughly reviewed and reexamined the issue of whether the labeling scheme set forth in the proposal should be promulgated. A careful analysis of the comments received in response to the proposal, as well as an examination of the Department's longstanding labeling policy, and the rationale behind this policy for ingredients of meat food products, in general, and, in particular, for the ingredient MS(S), along with Court decisions about MS(S), have led the Department to conclude that the proposed labeling scheme should be withdrawn.

The Department agrees with the commenters who opposed the proposal and who stated that if mechanically separated product is used, it should be identified in the ingredients statement of a finished product as MS(S). This is consistent with the Department's longstanding labeling policy which requires, in general, that the ingredients of a meat food product be listed on its label in the ingredients statement. This is also consistent with the Department's longstanding labeling policy for meat food products that contain MS(S) as an ingredient, which is designed to ensure that labels of meat food products that contain MS(S) are not false or misleading. This longstanding labeling policy is set forth in the Department's final rulemaking document on MP(S)P (43 FR 26416), as well as in the Department's 1982 final rulemaking document on MS(S) (47 FR 28214). The Department's final 1982 rulemaking document on MS(S) indicates that the Department had determined that material differences in composition and consistency place MS(S) outside the scope of product traditionally defined as meat, and that the characteristics of MS(S) are such that it should be defined as a distinctive, standardized product. Therefore, this rulemaking document indicates that MS(S) must be declared on finished product labels by the name specified in its definition and standard, which is MS(S). The rulemaking document notes that it is the distinctive character and separate regulatory standard of the product that are the basis for the ingredient declaration requirement, and not the product's wholesomeness or fitness for consumption or the level in the particular meat food product in which it is used as an ingredient. As indicated above, the Department's labeling requirements for MS(S) were upheld by the United States District Court and the United States Court of Appeals for the District of Columbia, and are currently set forth in the Department's regulations. The Department continues to believe that the aforementioned reasons for requiring the separate identification of MS(S) in the ingredients statement of a meat food product in which it is used are correct, and that the ingredients statement labeling requirement for MS(S) is necessary to meet the mandate of the Federal Meat Inspection Act that provides that labeling of meat food products should not be false or misleading.

The Department also agrees with those commenters who opposed the proposal based on a consumer's right to know when ingredients such as MS(S) are present in food. The Department agrees that consumers have a right to know when MS(S) is used as an ingredient in a product. The Department's longstanding labeling policy of requiring that MS(S) be separately identified in the ingredients statement of a product in which it is used ensures that consumers know when MS(S) is used in a meat food product.

The Department does not agree with those commenters who supported the proposal on the basis that products containing no more than 10 percent MS(S) would be more informatively labeled with an ingredients statement listing calcium content than with the term MS(S), because they assert that calcium content is relevant information about the finished products, whereas the term MS(S) describes the way in which a small constituent part of the product was produced. As stated previously, MS(S) is a distinctive, standardized ingredient. As such, it should be declared by its name specified in its definition and standard, consistent with the Department's longstanding labeling policy, in the ingredients statement of a meat food product in which it is used, in order to provide consumers with relevant information about this constituent of the product. Providing only calcium information on the label of a meat food product that contains MS(S) would not let consumers know that the distinctive, standardized product MS(S) was used in the product.

The Department also does not agree with those commenters who stated that disclosing the calcium content of a finished product is a labeling method which is superior to simply listing mechanically separated meat as an ingredient, because they assert that calcium content represents the only significant difference between products containing MS(S) and those that do not. As noted in the Department's 1982 final rulemaking document on MS(S), the consistency of this product and its content of bone, bone marrow, and certain minerals, as well as muscle tissue, are materially different from meat. The Department has determined that its characteristics are such that it should be defined as a distinctive, standardized product. Therefore, it cannot be concluded that calcium content represents the only significant difference between products that contain and those that do not contain MS(S). As made clear in the final 1982 rulemaking document on MS(S), the question of whether or not there needs to be any calcium content labeling for products that contain MS(S) is a separate question from whether MS(S) should be separately identified on the label of a product in which it is used. The purpose of listing MS(S) in the ingredients statement of a product in which it is used is to inform all consumers of its use in a product, while the purpose of providing calcium content labeling, under the circumstances set forth in the Department's current regulations, is to ensure that a more limited population, those persons on calcium-restricted diets, are informed when there is a meaningful increase in the total calcium content of a meat food product.

The Department has also considered with some care the comments submitted by some industry representatives that imposing labeling requirements on MS(S) while not imposing similar requirements on mechanically deboned poultry (MDP) is inconsistent and

inequitable. This issue has also been raised in a suit recently filed in the United States District Court for the District of Columbia (*Bob Evans Farms, Inc., et al.* v. *Espy*, C.A. No. 93–0104). As the government recently advised the Court, the Department has decided to issue an Advance Notice of Proposed Rulemaking to solicit comments to aid it in determining whether USDA should propose a regulation with respect to labeling regarding MDP.

Therefore, the proposed rule published on September 9, 1988 (53 FR 35089), is hereby withdrawn.

Done at Washington, DC, on April 12, 1993.

Kenneth C. Clayton,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93–8909 Filed 4–15–93; 8:45 am]

BILLING CODE 3410-DM-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 20

Radiological Criteria for Decommissioning of NRC-Licensed Facilities; Workshop

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of workshop.

SUMMARY: The Nuclear Regulatory Commission (NRC) is preparing to initiate an enhanced participatory rulemaking on establishing the radiological criteria for the decommissioning of NRC-licensed facilities. The Commission intends to enhance the participation of affected interests in the rulemaking by soliciting commentary from these interests on the rulemaking issues before the staff develops the draft proposed rule. The Commission plans to conduct a series of workshops to solicit commentary from affected interests on the fundamental approaches and issues that must be addressed in establishing the radiological criteria for decommissioning. The sixth workshop will be held in Atlanta, Georgia on April 29 and 30, 1993 and will be open to the public.

DATES: April 29, 1993 from 9 a.m. to 5:45 p.m.; April 30, 1993, from 8:30 a.m. to 4 p.m. In addition, the staff of the Nuclear Regulatory Commission and the Environmental Protection Agency will be available the evening before the workshop, Wednesday, April 28, 1993, from 7 p.m. to 9:30 p.m. to provide information on the intent and format of the workshop and to receive comments from members of the public who may not be able to attend the workshop. The workshop agenda also provides for scheduled opportunities throughout the workshop for the public to comment on the rulemaking issues and the workshop discussions. The scheduled public comment periods include: 12:15 p.m.–12:45 p.m.; 3:15 p.m.–3:30 p.m.; and 5:15 p.m.–5:45 p.m. on Thursday, April 29; and 10 a.m.–10:15 a.m.; 12 p.m.–12:30 p.m.; and 2:45 p.m.–3:15 p.m. on Friday, April 30. All sessions will be held at the INFORUM at Atlanta Market Center (Rooms 2 and 3 near Techwood Street, 250 Williams Street NW., Atlanta, Georgia. Hotel accommodations are at the Westin Peachtree Plaza, 210 Peachtree Street NW. at International Boulevard, Atlanta, Georgia, 404–659–1400.

As discussed later in this notice, the workshop discussions will focus on the issues and approaches identified in a Rulemaking Issues Paper prepared by the NRC staff. The Commission will accept written comments on the Rulemaking Issues Paper from the public, as well as from workshop participants. Written comments should be submitted by May 28, 1993.

ADDRESSES: Send written comments on the Rulemaking Issues Paper to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555. ATTN: Docketing and Service Branch. Hand deliver comments to 11555 Rockville Pike, Rockville, Maryland between 7:45 a.m. and 4:15 p.m. on Federal workdays. The Rulemaking Issues Paper is available from Francis X. Cameron (See "FOR FURTHER INFORMATION CONTACT").

FOR FURTHER INFORMATION CONTACT: Francis X. Cameron, Special Counsel for Public Liaison and Waste Management, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington DC 20555, Telephone: 301–504–1642.

SUPPLEMENTARY INFORMATION:

Background

The NRC has the statutory responsibility for protection of health and safety related to the use of source, byproduct, and special nuclear material under the Atomic Energy Act. The NRC believes that one portion of this responsibility is to ensure the safe and timely decommissioning of nuclear facilities which it licenses and to provide guidance to licensees on how to plan for and prepare their sites for decommissioning. Once licensed activities have ceased, licensees are required to decommission their facilities so that their licenses may be terminated. This requires that the radioactivity in land, groundwater, buildings, and equipment resulting from the licensed operation be reduced to levels that allow the property to be released for unrestricted use. Licensees must then demonstrate that all facilities have been properly decontaminated and that radioactive material has been transferred to authorized recipients. Confirmatory surveys are conducted by NRC, where appropriate, to verify that sites meet NRC radiological criteria for decommissioning.

The types of nuclear fuel cycle facilities that will require decommissioning include nuclear power plants; non-power (research and test) reactors; fuel fabrication plants, uranium hexafluoride production plants, and independent spent fuel storage installations. In addition there are currently about 24,000 materials licensees. About one third of these are NRC licensees, while the remainder are licensed by Agreement States acting under the authority of the Atomic Energy Act, section 274. These licensees include universities, medical institutions, radioactive source manufacturers, and companies that use radioisotopes for industrial purposes. About 50% of NRC's 7,500 materials licensees use either sealed radioactive sources or small amounts of short-lived radioactive materials. Decommissioning of these facilities should be relatively simple because there is usually little or no residual radioactive contamination. Of the remaining 50%, a small number (e.g. radioactive source manufacturers, radiopharmaceutical producers, and radioactive ore processors) conduct operations that could produce substantial radioactive contamination in portions of the facility. These facilities, like the fuel cycle facilities identified above, must be decontaminated before they can be safely released for unrestricted use.

Several hundred NRC and Agreement State licenses are terminated each year. The majority of these licenses involve limited operations, produce little or no radioactive contamination, and do not present complex decommissioning problems or potential risks to public health or the environment from residual contamination. However, as the nuclear industry matures, it is expected that more and more of the larger nuclear facilities that have been operating for a number of years will reach the end of their useful lives and be decommissioned. Therefore, both the number and complexity of facilities that will require decommissioning is expected to increase.

The Commission believes that there is a need to incorporate into its regulations radiological criteria for termination of licenses and release of land and structures for unrestricted use. The intent of this action would be to provide a clear and consistent regulatory basis for determining the extent to which lands and structures must be decontaminated before a site can be decommissioned. The Commission believes that inclusion of criteria in the regulations would result in more efficient and consistent licensing actions related to the numerous and frequently complex site decontamination and decommissioning activities anticipated in the future. A rulemaking effort would also provide an opportunity to reassess the basis for the residual contamination levels contained in existing guidance in light of changes in basic radiation protection standards and decommissioning experience obtained during the past 15 years.

The new criteria would apply to the decommissioning of power reactors, non-power reactors, fuel reprocessing plants, fuel fabrication plants, uranium hexafluoride production plants, independent spent fuel storage installations, and materials licenses. The criteria would apply to nuclear facilities that operate through their normal lifetime, as well as to those that may be shut down prematurely. The proposed criteria would not apply to uranium (other than source material) mines and mill tailings, high-level waste repositories, or low-level waste disposal facilities.

Until the new criteria are in place, the Commission intends to proceed with the decommissioning of nuclear facilities on a site-specific basis as the need arises considering existing criteria. Case and activity-specific risk decisions will continue to be made as necessary during the pendency of this process.

The Enhanced Participatory Rulemaking

The Commission believes it is desirable to provide for early and comprehensive input from affected interests on important public health and safety issues, such as the development of radiological criteria for decommissioning. Accordingly, the Commission is initiating an enhanced participatory rulemaking to establish these criteria. The objective of the rulemaking is to enhance the participation of affected interests in the rulemaking by soliciting commentary from these interests on the rulemaking issues before the NRC staff develops the draft proposed rule. The NRC staff will consider this commentary in the development of the draft proposed rule, as well as document how these comments were considered in arriving at a regulatory approach. The Commission believes that this will be an effective method for illuminating the decision making process on complex and controversial public health and safety issues. This approach will ensure that the important issues have been identified; will assist in identifying potential information gaps or implementation problems; and will facilitate the development of potential solutions to address the concerns that affected interests may have in regard to the rulemaking.

The early involvement of affected interests in the development of the draft proposed rule will be accomplished through a series of workshops. A workshop format was selected because it will provide representatives of the affected interests with an opportunity to discuss the rulemaking issues with one another and to question one another about their respective positions and concerns. Although the workshops are intended to foster a clearer understanding of the positions and concerns of the affected interests, as well as to identify areas of agreement and disagreement, it is not the intent of the workshop process to attempt to develop a consensus agreement on the rulemaking issues. In addition to the commentary from the workshop participants, the workshops will be open to the public and the public will be provided with the opportunity to comment on the rulemaking issues and the workshop discussions at discrete intervals during the workshops.

The workshops were initially announced in the **Federal Register** on December 11, 1992 (57 FR 58727). The complete schedule for the workshops is:

Jan. 27 and 28, 1993, Chicago, IL.
Feb. 23 and 24, 1993, San Francisco, CA.
Mar. 12 and 13, 1993, Boston, MA.
Mar. 23 and 24, 1993, Dallas, TX.
Apr. 13 and 14, 1993, Philadelphia, PA.
Apr. 29 and 30, 1993, Atlanta, GA.
May 6 and 7, 1993, Washington, DC.

The normal process for conducting Commission rulemakings is NRC staff development of a draft proposed rule for Commission review and approval, publication of the proposed rule for public comment, consideration of the comments by the NRC staff, and preparation of a draft final rule for Commission approval. In the enhanced participatory rulemaking, not only will comments be solicited before the NRC staff prepares a draft proposed rule, but the mechanism for soliciting these early comments will also provide an opportunity for the affected interests and the NRC staff to discuss the issues with each other, rather than relying on the traditional one-to-one written correspondence with the NRC staff. After Commission review and approval of the draft proposed rule that is developed using the workshop commentary, the general process of issuing the proposed rule for public comment, NRC staff evaluation of comments, and preparation of a draft final rule for Commission approval, will occur.

Participants

In order to have a manageable discussion among the workshop participants, the number of participants in each workshop must be limited. Based on discussions with experts on workshop facilitation, the NRC staff believes that the optimum size of the workshop group is fifteen to twenty participants. Due to differing levels of interest in each region, the actual number of participants in any one workshop, as well as the number of participants that represent a particular interest in any one workshop, may vary. Invitations to attend the workshops will be extended by the NRC staff using several selection criteria. First, to ensure that the Commission has the benefit of the spectrum of viewpoints on the issues, the NRC staff is attempting to achieve the participation of the full range of interests that may be affected by the rulemaking. The NRC staff has identified several general interests that will be used to select specific workshop participants—state governments, local governments, tribal governments, Federal agencies, citizens groups, nuclear utilities, fuel cycle facilities, and non-fuel cycle facilities. In addition to these interests, the staff also plans to invite representatives from the contracting industry that performs decommissioning work and representatives from professional societies, such as the Health Physics Society and the American Nuclear Society. The NRC anticipates that most of the participants will be representatives of organizations. However, it is also possible that there may be a few participants who, because of their expertise and influence, will participate without any organizational affiliation.

The second selection criterion is the ability of the participant to knowledgeably discuss the full range of rulemaking issues. The NRC staff wishes to ensure that the workshops will elicit informed discussions of options and approaches, and the rationale for those

options and approaches, rather than simple statements of opinion. The NRC staff's identification of potential participants has been based on an evaluation of such factors as the extent of a potential participant's experience with a broad range of radiation protection issues and types of nuclear facilities, specific experience with the decommissioning issue, and the extent of a potential participant's substantive comment and participation on previous Commission regulatory or licensing actions.

The third criterion emphasizes participation from organizations within the region encompassed by the workshop. As much as practicable, those organizations that primarily operate within the region, as opposed to regional units of national organizations, will have priority in terms of participating in the corresponding regional workshops. Organizations with a national standing will be part of the "national" workshop to be held in Washington, DC.

Workshop Format

To assure that each workshop addresses the issues in a consistent manner, the workshops will have a common pre-defined scope and agenda focused on the Rulemaking Issues Paper discussed below. However, the workshop format will be sufficiently flexible to allow for the introduction of any additional issues that the participants may want to raise. At each workshop, the NRC staff will begin each discussion period with a brief overview of the rulemaking issues to be discussed and the remainder of the workshop will be devoted to a discussion of the issues by the participants. The workshop commentary will be transcribed and made available to participants and to the public.

Personnel from The Keystone Center, a nonprofit organization located in Keystone, Colorado, will serve as neutral facilitators for each workshop. The facilitators will chair the workshop sessions and ensure that participants are given an opportunity to express their viewpoints, assist participants in articulating their interests, ensure that participants are given the opportunity to question each other about their respective viewpoints, and assist in keeping the discussion moving at a pace that will allow all major issue areas to be addressed.

Rulemaking Issues Paper

The NRC staff has prepared a Rulemaking Issues Paper to be used as a focal point for the workshop discussions. This paper, which will be distributed to participants in advance of the workshops, sets forth in neutral terms the issues that must be addressed in the rulemaking, as well as background information on the nature and extent of the problem to be addressed. In framing the issues and approaches discussed in the Rulemaking Issues Paper, the NRC staff has attempted to anticipate the variety of views that exist on these approaches and issues. The paper will provide assistance to the participants as they prepare for the workshops, suggest the workshop agenda, and establish the level of technical discussion that can be expected at the workshops. The workshop discussions are intended to be used by the staff in developing the draft proposed rule. Prior to the workshops no staff positions will be taken on the rulemaking approaches and issues identified in the Rulemaking Issues Paper. As noted earlier, to the extent that the Rulemaking Issues Paper fails to identify a pertinent issue, this may be corrected at the workshop sessions.

The discussion of issues is divided into two parts. First are two primary issues dealing with: (1) The objectives for developing radiological criteria; and (2) Application of practicality considerations. The objectives constitute the fundamental approach to the establishment of the radiological criteria, and the NRC staff has identified four distinct possibilities including: (1) Risk Limits, which is the establishment of limiting values above which the risks to the public are deemed unacceptable, but allows for criteria to be set below the limit using practicality considerations; (2) Risk Goals, where a goal is selected and practicality considerations are used to establish criteria as close to the goal as practical; (3) Best Effort, where the technology for decontamination considered to be the best available is applied; and (4) Return to Preexisting Background, where the decontamination would continue until the radiological conditions were the same as existed prior to the licensed activities.

Following the primary issues are several secondary issues that are related to the discussions of the primary issues, but which the NRC staff believe warrant separate presentations and discussions. These secondary issues include the time frame for close calculation, the individuals or groups to be protected, the use of separate criteria for specific exposure pathways such as groundwater, the treatment of radon, and the treatment of previously buried materials.

The Rulemaking Issues Paper will be provided to each potential workshop participant. Additional copies will be available to members of the public in attendance at the workshop. Copies will also be available from the NRC staff contact identified above. In addition to the comments on the Rulemaking Issues Paper provided at the workshops, the Commission is also receptive to the submittal of written comments on the rulemaking issues, as noted under the heading "DATES".

Dated at Rockville, MD this 12th day of April, 1993.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,

Secretary of the Commission.

[FR Doc. 93–8932 Filed 4–15–93; 8:45 am]

BILLING CODE 7590–01–M

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10 CFR Part 72

RIN 3150–AE15

List of Approved Spent Fuel Storage Casks: Additions; Extension of Comment Period

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule: Extension of comment period.

SUMMARY: On January 22, 1993 (58 FR 5301), NRC published a notice in the **Federal Register** extending the public comment period for a portion of a proposed rule published on June 26, 1992 (57 FR 28645), which would amend NRC's list of approved spent fuel storage casks by adding two casks to the list. Holders of power reactor operating licenses would then be authorized to store spent fuel in these approved casks under a general license. The January 1993 notice explained that, pursuant to the provisions of 10 CFR 2.790(c), the NRC was releasing certain information which would form the basis of this rule for one of the two casks and which was previously categorized as proprietary information. The notice also explained that additional supplemental information relating to the second cask (the TN–24) would be handled in a separate future notice. The NRC has now completed its evaluation of the TN–24 cask data. Additional information relating only to the TN–24 cask is being placed in the PDR at this time. Therefore, the comment period for the proposed rule, with respect to the TN–24 cask only, is being reopened for 30 days to allow comments on the additional information.

DATES: Although the comment period expires May 17, 1993, comments

received after this date will be considered if it is practical to do so but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Send written comments or suggestions to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Gordon E. Gundersen, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 492–3803, or Mr. James F. Schneider, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone (301) 504–2692.

SUPPLEMENTARY INFORMATION:

In connection with the portion of this rulemaking pertaining only to the TN–24 cask, and pursuant to 10 CFR 2.790(c), NRC is placing in the NRC Public Document Room portions of the TN–24 cask vendor's Safety Analysis Report (SAR), as well as certain information of the TN–24 cask vendor, supporting its respective SAR, which the vendor previously claimed to be proprietary. Although NRC has not yet approved or adopted a final rule for the TN–24 cask in the present rulemaking, NRC is now disclosing the vendor's information described above, in advance of any final rule, during the proposed rulemaking stage for the TN–24 cask.

The information of the TN–24 cask vendor being disclosed at this time provides added detail to the information on that cask NRC previously placed in the NRC Public Document Room at the outset of this rulemaking. It complements and supplements the design information on the TN–24 cask already disclosed, providing further detail on such matters as the TN–24 cask vendor's design calculations and specific data inputs for models used by the vendor for such calculations, as well as cask design details. The information being disclosed therefore provides additional specificity for the public about the technical information on the TN–24 cask that was considered by the NRC staff in preparing the principal NRC documents on that cask, that is, the proposed TN–24 cask Certificate of Compliance and the associated NRC staff Safety Evaluation Report and related Environmental Assessment which were previously placed in the NRC Public Document Room at the outset of this proposed rulemaking.

By disclosing the TN–24 cask vendor's information described above, in advance of any final rule on that cask, NRC is giving the public an additional opportunity to review the content of such information, and the Agency is accordingly extending the public comment period on the TN–24 cask only for an additional 30 days for this limited purpose, in case members of the public wish to submit additional comments or supplement their prior comments in this proceeding regarding the TN–24 cask. However, the Agency will consider all comments already received to date (which are available in the NRC Public Document Room) that pertain to the TN–24 cask, and it is therefore unnecessary for commenters to repeat or resubmit prior comments. Accordingly, commenters are specifically requested to limit their written submissions to comments based on a review of the TN–24 cask vendor's information now being put in the NRC Public Document Room.

Dated at Rockville, Maryland, this 12th day of April 1993.

For the Nuclear Regulatory Commission.

James M. Taylor,

Executive Director for Operations.

[FR Doc. 93–8933 Filed 4–15–93; 8:45 am]

BILLING CODE 7590-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 92–NM–217–AD]

Airworthiness Directives; Airbus Industrie Model A320 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Airbus Industrie Model A320 series airplanes. This proposal would require modification of the brake steering control unit (BSCU). This proposal is prompted by several reports that the BSCU on these airplanes allowed a 90-degree rotation of the nose gear after landing, resulting in significant damage to the wheels. The actions specified by the proposed AD are intended to prevent a 90-degree rotation of the nose gear, which could cause subsequent failure of the nose gear tires and wheels and the loss of directional control of the airplane while on the ground.

DATES: Comments must be received by June 14, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–217–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Mr. Greg Holt, Aerospace Engineer, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (206) 227–2140; fax (206) 227–1320.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 92–NM–217–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 92–NM–217–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The Direction Générale de l'Aviation Civile (DGAC), which is the airworthiness authority for France, recently notified the FAA that an unsafe condition may exist on certain Airbus Industrie Model A320 series airplanes. The DGAC advises that several operators of these airplanes have reported that certain brake steering control units (BSCU) caused the nose gear to rotate 90 degrees after landing, resulting in significant wheel damage. One of the reported incidents occurred after an aborted takeoff. The cause of these occurrences has been attributed to discrepancies found within the functional software of the BSCU. This condition, if not corrected, could result in failure of the nose gear tires and wheels and the loss of directional control of the airplane while on the ground.

Airbus Industrie has issued Service Bulletin A320–32–1094, Revision 2, dated November 25, 1992, which describes procedures for modification of the BSCU. Accomplishment of the modification involves upgrading the currently-installed standard 5.2 BSCU functional software to a new standard 5.3, which includes reprogramming of certain software for each system of the BSCU. Accomplishment of this modification would allow (1) activation of the nose wheel steering control as soon as the main landing gear touches the ground at landing, and (2) progressive amplitude authority from 130 to 40 knots. The DGAC classified this service bulletin as mandatory and issued French Airworthiness Directive 92–117–025(B), dated May 13, 1992, in order to assure the continued airworthiness of these airplanes in France.

This airplane model is manufactured in France and is type certificated for operation in the United States under the provisions of § 21.29 of the Federal Aviation Regulations and the applicable bilateral airworthiness agreement. Pursuant to this bilateral airworthiness agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of this type design that are certificated for operation in the United States.

Since an unsafe condition has been identified that is likely to exist or develop on other airplanes of the same type design registered in the United States, the proposed AD would require modification of the BSCU. The actions would be required to be accomplished in accordance with the service bulletin described previously.

The FAA estimates that 52 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 1 work hour per airplane to accomplish the proposed actions, and that the average labor rate is $55 per work hour. Required parts would be supplied by the vendor at no cost to operators. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $2,860, or $55 per airplane. This total cost figure assumes that no operator has yet accomplished the proposed requirements of this AD action.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES."

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Airbus Industrie: Docket 92–NM–217–AD.

Applicability: Model A320 series airplanes equipped with twin wheel main landing gears on which Airbus Industrie Service Bulletin A320–32–1094 or Airbus Industrie Modification 22990 has not been accomplished; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent failure of the nose gear tires and wheels and the loss of directional control, accomplish the following:

(a) Within 6 months after the effective date of this AD, modify the brake steering control unit (BSCU) in accordance with Airbus Industrie Service Bulletin A320–32–1094, Revision 2, dated November 25, 1992.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on April 12, 1993.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–8923 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–13–P

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14 CFR Part 39

[Docket No. 93–CE–23–AD]

Airworthiness Directives; Beech Aircraft Corporation Models B90, C90, and C90A Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes to adopt a new airworthiness directive (AD) that would apply to certain Beech Aircraft Corporation (Beech) Models B90, C90, and C90A airplanes. The proposed action would require inspecting the inboard nipple on the leading edge fuel cell for cracks or fuel leaks, repairing if cracks or fuel leaks are found, and replacing the fuel interconnect assembly. Reports of fuel line misalignment that resulted in cracking of the fuel cell nipples at the inboard wing root of the affected airplanes prompted the proposed action. The actions specified by the proposed AD are intended to prevent failure of these fuel cell nipples caused by cracking and fuel leaks, which, if not detected and corrected, could result in an airplane fire.

DATES: Comments must be received on or before June 24, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–CE–23–AD, Room 1558, 601 E. 12th Street, Kansas City, Missouri 64106. Comments may be inspected at this location between 8 a.m. and 4 p.m., Monday through Friday, holidays excepted.

Service information that applies to the proposed AD may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. This information also may be examined at the Rules Docket at the address above.

FOR FURTHER INFORMATION CONTACT: Charles D. Riddle, Aerospace Engineer, FAA, Wichita Aircraft Certification Office, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209; Telephone (316) 946–4144; Facsimile (316) 946–4407.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications should identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report that summarizes each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 93–CE–23–AD." The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Central Region, Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93–CE–23–AD, room 1558, 601 E. 12th Street, Kansas City, Missouri 64106.

Discussion

The FAA has received several reports of cracked fuel cell nipples at the inboard wing root on certain Beech Models B90, C90, and C90A airplanes. The fuel lines of the referenced incidents were misaligned, which placed the fuel cell nipple at an extreme angle and overstressed the cell material. This resulted in cracks and, in some instances, fuel leaks.

Beech has issued Service Bulletin (SB) No. 2475, dated February 1993, which specifies procedures for accomplishing the following on certain Beech Models B90, C90, and C90A airplanes: (1) Inspecting the inboard nipple on the leading edge fuel cell for cracks and fuel leaks; and (2) replacing the fuel interconnect tube assembly.

After examining the circumstances and reviewing all available information related to the incidents described above, the FAA has determined that AD action should be taken to prevent failure of the leading edge fuel cell nipples caused by cracking and fuel leaks, which, if not detected and corrected, could result in an airplane fire.

Since an unsafe condition has been identified that is likely to exist or develop in other Beech Models B90, C90, and C90A airplanes of the same type design, the proposed AD would require (1) inspecting the inboard nipple on the leading edge fuel cell for cracks or fuel leaks, and repairing any cracks or fuel leaks; and (2) replacing the fuel interconnect tube assembly. The proposed inspection and fuel interconnect tube assembly replacement would be accomplished in accordance with Beech SB No. 2475, dated February 1993. If necessary, the proposed repair would be accomplished in accordance with procedures specified in the applicable maintenance manual.

The FAA estimates that 572 airplanes in the U.S. registry would be affected by the proposed AD, that it would take approximately 6 workhours per airplane to accomplish the proposed action, and that the average labor rate is approximately $55 an hour. Parts cost approximately $70 per airplane. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $228,800. These figures take into account that none of the affected airplanes have accomplished the proposed actions.

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this action (1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action has been placed in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption "ADDRESSES".

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§39.13 [Amended]

2. Section 39.13 is amended by adding the following new AD:

Beech Aircraft Corporation: Docket No. 93–CE–23–AD.

Applicability: Models B90, C90, and C90A airplanes (serial numbers LJ–489 through LJ–1318), certificated in any category.

Compliance: Required within the next 150 hours time-in-service after the effective date of this AD, unless already accomplished.

To prevent failure of the leading edge fuel cell nipples caused by cracking and fuel leaks, which, if not detected and corrected, could result in an airplane fire, accomplish the following:

(a) Inspect the inboard nipple on the leading edge fuel cell for cracks or fuel leaks in accordance with Part I of the ACCOMPLISHMENT INSTRUCTIONS section of Beech Service Bulletin (SB) No. 2475, dated February 1993. If cracks or fuel leaks are found, prior to further flight, repair the fuel cells in accordance with procedures specified in the applicable maintenance manual.

(b) Replace the fuel interconnect tube assembly in accordance with Part II of the ACCOMPLISHMENT INSTRUCTIONS section of the Beech SB No. 2475, dated February 1993.

(c) Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) An alternative method of compliance or adjustment of the compliance time that provides an equivalent level of safety may be approved by the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Mid-Continent Airport, Wichita, Kansas 67209. The request shall be forwarded through an appropriate FAA Maintenance Inspector, who may add comments and then send it to the Manager, Wichita Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Wichita Aircraft Certification Office.

(e) Service information that applies to this AD may be obtained from the Beech Aircraft Corporation, P.O. Box 85, Wichita, Kansas 67201–0085. This information may also be inspected at the FAA, Central Region, Office of the Assistant Chief Counsel, Room 1558, 601 E. 12th Street, Kansas City, Missouri.

Issued in Kansas City, Missouri, on April 12, 1993.

Gerald W. Pierce

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 93–8927 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–13–P

Coast Guard

33 CFR Part 165

[CGD1 93–017]

Safety Zone: USS John F. Kennedy, New York Harbor, New York and New Jersey

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a moving safety zone for the USS John F. Kennedy as it proceeds through the Port of New York during the week of May 26 to June 1, 1993. This moving safety zone in the Port of New York is needed to protect the maritime community from the possible hazards associated with the movement of a large aircraft carrier, with limited maneuverability, operating in restricted waters. This safety zone will be established 500 yards fore and aft, and 200 yards on either side of the USS John F. Kennedy any time the vessel is underway in the Port of New York. Entry into or movement within the Safety Zone will be prohibited unless authorized by the Captain of the Port, New York.

DATES: Comments must be received on or before May 17, 1993.

ADDRESSES: Comments should be mailed to Commander, Coast Guard Group New York, Bldg. 108, Governors Island, New York 10004–5096, or may be delivered to the Waterways Management Office, Bldg. 109, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Any person wishing to visit the office must contact the Waterways Management Office at (212) 668–7933 to obtain advance clearance due to the fact that Governors Island is a military installation with limited access.

FOR FURTHER INFORMATION CONTACT: Lieutenant (junior grade) J. J. Gleason, Waterways Management Officer, Coast Guard Group New York (212) 668–7933.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their name and address, identify this notice (CGD1–93–017), the specific section of the proposal to which their comments apply, and give reasons for each comment. Persons wanting acknowledgement of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Project Manager at the address under "**ADDRESSES.**" If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register.**

Drafting Information

The drafters of this notice are LTJG J.J. Gleason, Project Manager, Captain of the Port, New York and LCDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

Background and Purpose

On February 16, 1993, the Intrepid Air Space Museum submitted a request to hold a parade of U.S. and foreign Naval and Coast Guard ships through the Port of New York and New Jersey on May 26, 1993. The USS John F. Kennedy was scheduled to be a participant in this parade, however due to the height of the tide and the vertical clearance of the Verrazano-Narrows Bridge the USS John F. Kennedy will not be able to enter the Port of New York at the time the parade is scheduled. Therefore the Coast Guard proposes to establish this moving safety zone within the Port of New York surrounding the USS John F. Kennedy while it is underway.

This regulation is needed to protect the maritime public from any possible hazards associated with a large naval vessel, with limited maneuverability, operating in restricted waters.

No vessel will be permitted to enter or move within this area unless permitted to do so by Captain of the Port, New York.

Discussion of Proposed Amendments

This safety zone will go into effect when the USS John F. Kennedy reaches the Ambrose Light at approximately 11:30 a.m. on May 26, 1993 and at all times while the JFK is underway until it passes, outbound, the Ambrose Light at approximately 10 p.m. on June 1, 1993. This closure is needed to protect the maritime public from any possible hazards associated with an aircraft carrier, with limited maneuverability, operating in restricted waters. The proposed regulations would establish a moving safety zone 500 yards fore and aft, and 200 yards on either side of the JFK at any time it is underway during the week of May 26 to June 1, 1993.

Regulatory Evaluation

This proposal is not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). With room to maneuver around the zone, the waterways will not be completely closed. Due to the transient nature of this safety zone it will not affect any single location for a prolonged period of time. For the above reasons and the fact that commercial traffic will not be significantly delayed, the Coast Guard expects the economic impact of this proposal to be so minimal that a Regulatory Evaluation is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

For reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501).

Federalism

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this regulation and concluded that under section 2.B.2.c. of Commandant Instruction M16475.1B, it is an action under the Coast Guard's statutory authority to protect public safety, and thus is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Proposed Regulations

For reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5, 49 CFR 1.46.

2. A temporary section 165.T01–017 is added to read as follows:

§ 165.T01–017 USS John F. Kennedy, Port of New York And New Jersey

(a) *Location.* The safety zone includes all waters of the Port of New York and New Jersey in which the USS John F. Kennedy is transiting, at all times the vessel is underway between Ambrose Light and pier 88 in Manhattan.

(b) *Effective period.* This regulation will be effective at all times the JFK is underway, from the point the vessel arrives at the Ambrose Light, approximately 11:30 a.m. on May 26, 1993 until it departs the Ambrose Light at approximately 10 p.m. on June 1, 1993.

(c) *Regulations.* (1) All vessels must remain outside at least 500 yards fore and aft and 200 yards on either side of the vessel while underway unless authorized by the U.S. Coast Guard Captain of the Port, New York.

(2) All persons and vessels shall comply with the instructions of the COTP or Coast Guard designated personnel on scene. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the U.S. Coast Guard. Upon hearing five or more blasts from a U.S. Coast Guard vessel, the operator of a vessel shall proceed as directed.

Dated: March 29, 1993.

R.M. Larrabee,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 93–8990 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–14–M

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33 CFR Part 165

[CGD1 93–014]

Safety Zone: North Hempstead Memorial Day Fireworks, New York

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a safety zone for the North Hempstead Memorial Day Fireworks program. The event, sponsored by the town of North Hempstead, will take place on Friday, May 28, 1993, from 8 p.m. until 10 p.m. This safety zone in Hempstead Harbor is needed to protect the boating public from the hazards associated with fireworks exploding in the area.

DATES: Comments must be received on or before May 17, 1993.

ADDRESSES: Comments should be mailed to Commander, Coast Guard Group New York, Bldg. 108, Governors Island, New York 10004–5096, or may be delivered to the Waterways Management Office, Bldg. 109, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

Any person wishing to visit the office must contact the Waterways Management Office at (212) 668–7933 to obtain advance clearance due to the fact that Governors Island is a military installation with limited access.

FOR FURTHER INFORMATION CONTACT: Lieutenant (junior grade) J.J. Gleason, Waterways Management Officer, Coast Guard Group New York, (212) 668–7933.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this notice (CGD1–93–014) and the specific section of the proposal to which their comments apply, and give reasons for each comment. Persons wanting acknowledgment of receipt of comments should enclose a stamped, self-addressed postcard or envelope.

The Coast Guard will consider all comments received during the comment period. It may change this proposal in view of the comments. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Project Manager at the address under **ADDRESSES.** If it is determined that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register.**

Drafting Information

The drafters of this notice are LTJG J.J. Gleason, Project Manager, Captain of the Port, New York and LCDR J. Stieb, Project Attorney, First Coast Guard District, Legal Office.

Background and Purpose

On March 2, 1993, The town of North Hempstead submitted a request to hold

a fireworks program in Hempstead Harbor, New York. The proposed regulations would establish a safety zone in Hempstead Harbor in order to protect boaters from the hazards associated with the exploding of pyrotechnics in the area. No vessel would be permitted to enter or move within this area unless permitted to do so by the Coast Guard Captain of the Port, New York or the sponsor.

Discussion of Proposed Amendments

The Coast Guard proposes to establish a safety zone in the waters of Hempstead Harbor, New York. The safety zone will be in effect from 8 p.m. until 10 p.m. on May 28, 1993. This closure is needed to protect spectators and participants from the hazards that accompany a fireworks program.

Regulatory Evaluation

These regulations are not major under Executive Order 12291 and not significant under Department of Transportation Regulatory Policies and Procedures (44 FR 11040; February 26, 1979). Due to the limited duration of the event and the extensive advisories that will be made to the affected maritime community the Coast Guard expects the economic impact of this proposal to be so minimal that a Regulatory Evaluation is unnecessary.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), The Coast Guard must consider whether this proposal will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under Section 3 of the Small Business Act (15 U.S.C. 632).

For reasons set forth in the above Regulatory Evaluation, the Coast Guard certifies under 5 U.S.C. 605(b) that this proposal, if adopted, will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This proposal contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501).

Federalism

The Coast Guard has analyzed this action in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this proposal does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environment

The Coast Guard considered the environmental impact of this regulation and concluded that under section 2.B.2.c. of Commandant Instruction M16475.1B, it is an action under the Coast Guard's statutory authority to protect public safety, and thus is categorically excluded from further environmental documentation.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

Proposed Regulations

For reasons set out in the preamble, the Coast Guard proposes to amend 33 CFR part 165 as follows:

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5, 49 CFR 1.46.

2. A temporary section 165.T01–014 is added to read as follows:

§ 165.T01–014 Hempstead Memorial Day Fireworks, New York

(a) *Location.* The safety zone will include all waters within a 300 yard radius of three fireworks barges located at or near 40°49′52″ N and 73°39′12″ W in Hempstead Harbor.

(b) *Effective period.* This regulation will be effective from 8 P.M. until 10 P.M. on May 28, 1993. A rain date for the event is scheduled for May 29, 1993 from 8 P.M. until 10 P.M.

(c) *Regulations.* (1) No person or vessel may enter, transit, or remain in the regulated area during the effective period of regulation unless participating in the event as authorized by the sponsor or the Coast Guard.

(2) All persons and vessels shall comply with the instructions of the COTP or the designated on scene personnel. U.S. Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard. Upon hearing five or more blasts from a U.S. Coast Guard vessel, the operator of a vessel shall proceed as directed.

Dated: March 18, 1993.

R.M. Larrabee,

Captain, U.S. Coast Guard, Captain of the Port, New York.

[FR Doc. 93–8991 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–14–M

National Highway Traffic Safety Administration

49 CFR Part 571

[Docket No. 74–09; Notice 29]

RIN 2127–AE 80

Federal Motor Vehicle Safety Standards; Child Restraint Systems

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This notice proposes to amend labeling and other requirements of Federal Motor Vehicle Safety Standard No. 213, "Child Restraint Systems," for rear-facing child restraint systems. It would require that warning labels for these systems include a warning against using the restraint in any vehicle seating position equipped with an air bag. This notice also proposes to require that printed instructions for rear-facing seats include safety information about air bags.

DATES: Comments on this notice must be received by the agency no later than June 15, 1993. The proposed effective date is 180 days after the date of publication of a final rule.

ADDRESSES: Comments should refer to the docket number and notice number and be submitted in writing to: Docket Section, National Highway Traffic Safety Administration, room 5109, 400 Seventh Street SW., Washington, DC 20590. Telephone: (202) 366–5267. Docket hours are 9:30 a.m. to 4 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dr. George Mouchahoir, Office of Vehicle Safety Standards, National Highway Traffic Safety Administration, 400 Seventh Street SW., Washington, DC 20590 (telephone 202–366–4919).

SUPPLEMENTARY INFORMATION: This notice proposes to amend labeling and other requirements of Federal Motor Vehicle Safety Standard No. 213, "Child Restraint Systems," for rear-facing child restraint systems. It would require that warning labels for rear-facing restraint systems include a warning against using the restraint in any vehicle seating position equipped with an air bag. This notice also proposes to require that printed instructions for these seats include safety information about air bags. ("Rear-facing child restraint system" as used in this notice, refers to a child restraint system, except a car bed, in which a child is restrained facing in the direction opposite of the

normal direction of travel of the vehicle.)

Rear-facing seats position the child so that, in a crash, the forces are spread evenly across the child's back and shoulders, the strongest part of a child's body. As a result of this design, when the rear-facing seat is placed on a vehicle seat, the child restraint's seat back juts far forward of the vehicle seat back. If the vehicle seat is a front one and the vehicle is equipped with a passenger side air bag, the rear-facing seat back may rest on or may be located close to the part of the vehicle instrument panel containing the air bag.

Placing a rear-facing seat on such a vehicle seat raises a safety concern because an air bag, in order to deploy fast enough to protect occupants, must deploy at a high velocity. Concerns have arisen about the effect of the deploying air bag striking the rear-facing child restraint.

NHTSA has been pursuing these concerns both directly and indirectly. The agency has been closely monitoring the work of a task force on Child Restraint and Air Bag Interaction (CRABI) formed by the Society of Automotive Engineers. The task force is comprised of motor vehicle and child seat manufacturers and highway safety researchers. It has developed guidelines consisting of test procedures and test configurations (e.g., test dummies and a test fixture) that can be used for evaluating the interactions between child restraints and air bags. In addition, NHTSA has surveyed vehicle manufacturers about information they may have on this subject and research they may have conducted on this matter. In the Fall of 1991, the agency itself evaluated air bag interactions by conducting 30 mph dynamic sled tests with top- and mid-mounted air bags. (The data from these tests are available in Docket No. 74–09, General Reference.) NHTSA's findings from these tests indicate that air bags generally produce substantial increases in the values for the head injury criterion (HIC) and chest acceleration of dummies seated in rear-facing restraints, compared to dummies in rear-facing restraints tested with no air bag.

After conducting these tests and confirming the potential interaction problems, NHTSA sought to inform consumers about the air bag effect as quickly as possible. NHTSA issued a "Consumer Advisory" (December 10, 1991) which warned parents about using rear-facing child seats in vehicle seating positions equipped with air bags. The agency subsequently issued a proposal to require that certain warnings and information about the effect of air bags on rear-facing child seats be placed on labels in vehicles with air bags and provided in the vehicle owner's manual. (This proposal is included in the NPRM proposing to implement the provision in the NHTSA Authorization Act of 1991 requiring the agency to mandate air bags at all front outboard seating positions. 57 FR 59043, December 14, 1992.)

NHTSA is proposing today to supplement those actions by requiring information on the problem of the air bag interacting with the rear-facing child restraint to accompany each rear-facing restraint system. The need for the information appears stronger now than ever as more and more vehicles will become equipped with passenger-side air bags in the front seat, pursuant to the statutory air bag mandate. NHTSA tentatively concludes that today's proposal would help better inform parents about where to install rear-facing child restraint systems and that this would reduce the likelihood that the systems would be installed on vehicle seats equipped with an air bag.

NHTSA has previously announced the possibility of today's rulemaking in several undertakings. NHTSA's July 1991 "Planning Document on Potential Standard 213 Upgrade" (*See*, Docket No. 74–09, Notice 21) stated that rulemaking could result if the then-planned research (later conducted in Fall 1991) found a potential interaction problem between child restraints and air bags. NHTSA has also announced the possibility of rulemaking in the agency's quarterly industry meetings. NHTSA's consideration of consumer warnings on child seats was also announced in August of last year, in a petition denial. (Denial of Shelness Productions' rulemaking petition asking NHTSA to prohibit the installation of passenger side air bags, 57 FR 38462, August 25, 1992.) In the denial notice, NHTSA stated, "[T]he agency is contemplating rulemaking to require warnings about the potential adverse interaction of rear-facing child seats and air bags to be included in vehicle owner manuals and/or on rear-facing child seats."

Highlights of the Proposal

NHTSA proposes that a warning be included on the labeling on rear-facing child restraints and that information be included in the printed materials accompanying each rear-facing seat.

Warning Label

Rear-facing seats are currently required by Standard 213 to be labeled with warnings and other information about the proper use of the restraint (S5.2.1 and S5.2.2). NHTSA proposes to amend S5.5.2(k) to require child restraints that can be used in a rear-facing position to be labeled with whichever of the following statements is appropriate:

WARNING: WHEN THIS RESTRAINT IS USED IN A REAR-FACING MODE, DO NOT PLACE IN THE FRONT SEAT OF A VEHICLE THAT HAS A PASSENGER-SIDE AIR BAG.

or,

WARNING: DO NOT USE THIS INFANT RESTRAINT IN THE FRONT SEAT OF A VEHICLE THAT HAS A PASSENGER-SIDE AIR BAG.

The appropriateness of these statements would depend on whether the rear-facing restraint is a convertible seat (in which case, the first statement would be appropriate), or a rear-facing infant seat (in which case, the second statement would be appropriate). Determining the appropriateness of a labeling statement would not be a new responsibility for child seat manufacturers. S5.5.2(k) already requires them to make such a determination with respect to the instruction for positioning the rear-facing child restraint system.

The statement proposed by this notice is more detailed than the warning that NHTSA proposed in December 1992 to be labeled on vehicles equipped with a front passenger air bag. The earlier proposed warning would state: "Do not install rearward-facing child seats in any front passenger seat position." NHTSA tentatively concludes this statement would be appropriate as proposed for vehicles because it would appear on vehicles that have a passenger-side air bag. However, this statement might be overbroad if placed on a child seat, since it could imply that the rear-facing seat is incompatible with every front passenger seat on a vehicle, even those with no air bag. That implication could raise unnecessary concerns about the safety of rear-facing seats.

NHTSA has concluded the message proposed in this notice should achieve the following goals. The message should be brief, alerting consumers to and reminding them about a safety concern without causing "information overload." The message also should not inadvertently induce the consumer to misuse a restraint, such as might happen if the message were so loosely worded that consumers might conclude they could avoid the problem by simply turning the restraint around so that the child is forward-facing when the restraint is used in an air bag equipped seating position. The message also should be conspicuous. To this end,

NHTSA is proposing that the message must be on a yellow background, and be located so that the message is visible when the restraint is installed in the vehicle. NHTSA is considering requiring the message to be visible to a person in the driver's seat when the child restraint is installed rear-facing in the right front seat. NHTSA requests comments on these goals and on the extent to which the proposed requirements would ensure meeting those goals. Also, the agency seeks comment on the merits of a symbol or graphic that depicts the potential interaction problems between rear-facing child seats and air bags, and on the appropriate design of that symbol or graphic.

Printed Instructions

NHTSA proposes to amend S5.6.1 to add a requirement that the printed instructions for rear-facing seats must provide a warning against using rear-facing restraints at seating positions equipped with air bags and must explain the reasons for the warning and consequences of not following it. This proposal is similar to the December 1992 NPRM regarding the information that must be included in the vehicle owner's manual about the positioning of child restraints at positions equipped with an air bag. Comments are requested on whether S5.6.1 should specify the wording of the warning, on the appropriate language for such a warning, and on whether information about positioning child seats in general (i.e., not only rear-facing seats) in air bag equipped seating positions should be required.

This proposed rule would not have any retroactive effect. Under section 103(d) of the National Traffic and Motor Vehicle Safety Act (Safety Act; 15 U.S.C. 1392 (d)), whenever a Federal motor vehicle safety standard is in effect, a state may not adopt or maintain a safety standard applicable to the same aspect of performance which is not identical to the Federal standard, except to the extent that the state requirement imposes a higher level of performance and applies only to vehicles procured for the State's use. Section 105 of the Safety Act (15 U.S.C. 1394) sets forth a procedure for judicial review of final rules establishing, amending or revoking Federal motor vehicle safety standards. That section does not require submission of a petition for reconsideration or other administrative proceedings before parties may file suit in court.

Rulemaking Analyses and Notices

Executive Order 12291 (Federal Regulation) and DOT Regulatory Policies and Procedures

NHTSA has examined the impact of this rulemaking action and determined that it is not major within the meaning of Executive Order 12291 or significant within the meaning of the Department of Transportation's regulatory policies and procedures. NHTSA has prepared a preliminary regulatory evaluation (PRE) for this notice which discusses the potential costs, benefits and other impacts of this regulatory action. A copy of this PRE has been placed in the docket for this rulemaking action. Interested persons may obtain copies of this PRE by writing to the docket section at the address provided at the beginning of this notice.

To briefly summarize the PRE, NHTSA estimates that the consumer cost of the labeling proposals in this notice ranges from $0.09 to $0.17 per child restraint. The total annual cost will range from $350,280 to $661,640. This cost is expected to be even smaller if the proposed warning statement is placed on the existing FMVSS No. 213 label.

The PRE also estimates that, assuming full effectiveness of the proposed warning, two to four lives will be saved and 445 injuries will be reduced a year.

Regulatory Flexibility Act

NHTSA has considered the effects of this rulemaking action under the Regulatory Flexibility Act. I hereby certify that it would not have a significant economic impact on a substantial number of small entities. Of the 11 current child restraint manufacturers known to the agency (not counting factory-installed built-in restraints), there are three that would qualify as small businesses. These businesses do not comprise a substantial number of small entities that are affected by this rule.

Regardless of the number of small businesses, the rule will not have a significant economic impact on these entities. Infant seats range in cost between $20 and $82, with most costing about $30. Convertible seats (which are designed for use by both an infant and toddler) range in cost between $45 and $120, with most costing about $50. If the entire $0.17 cost of the rule were added to the cost of the restraint, the typical infant restraint would increase in price by only 0.57 percent and the typical convertible seat, by only 0.34 percent. Small organizations and governmental jurisdictions might be affected by the rule if these entities procure child restraint systems for programs such as loaner programs. While the cost of the restraint could increase, loaner program procurements would not be significantly affected. A program that had a fixed amount of money would have its procurements reduced by only 0.34 to 0.57 percent. Thus, regardless of the number of small organizations and governmental jurisdictions, NHTSA concludes the proposed rule would not have a significant economic impact on these entities.

Executive Order 12612

This proposed rule has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and the agency has determined that this proposal does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

National Environment Policy Act

NHTSA has analyzed this rulemaking action for the purposes of the National Environmental Policy Act. The agency has determined that implementation of this action would not have any significant impact on the quality of the human environment.

Comments on the Proposal

Interested persons are invited to submit comments on the proposal. It is requested, but not required, that 10 copies be submitted.

All comments must not exceed 15 pages in length. (49 CFR 553.21). Necessary attachments may be appended to these submissions without regard to the 15-page limit. This limitation is intended to encourage commenters to detail their primary arguments in a concise fashion.

If a commenter wishes to submit certain information under a claim of confidentiality, three copies of the complete submission, including purportedly confidential business information, should be submitted to the Chief Counsel, NHTSA, at the street address given above, and seven copies from which the purportedly confidential information has been deleted should be submitted to the Docket Section. A request for confidentiality should be accompanied by a cover letter setting forth the information specified in the agency's confidential business information regulation. 49 CFR part 512.

All comments received before the close of business on the comment closing date indicated above for the proposal will be considered, and will be available for examination in the docket at the above address both before and after that date. To the extent possible,

comments filed after the closing date will also be considered. Comments received too late for consideration in regard to the final rule will be considered as suggestions for further rulemaking action. Comments on the proposal will be available for inspection in the docket. The NHTSA will continue to file relevant information as it becomes available in the docket after the closing date, and it is recommended that interested persons continue to examine the docket for new material.

Those persons desiring to be notified upon receipt of their comments in the rules docket should enclose a self-addressed, stamped postcard in the envelope with comments. Upon receiving the comments, the docket supervisor will return the postcard by mail.

List of Subjects in 49 CFR Part 571

Imports, Motor vehicle safety, Motor vehicles.

PART 571—[Amended]

In consideration of the foregoing, NHTSA proposes to amend 49 CFR part 571 as set forth below.

1. The authority citation for part 571 would continue to read as follows:

Authority: 15 U.S.C. 1392, 1401, 1403, 1407; delegation of authority at 49 CFR 1.50.

§ 571.213 [Amended]

2. In § 571.213, S5.5.2(k) would be revised to read as follows:

* * * * *

(k) In the case of each child restraint system that can be used in a rear-facing position, the following statements:

(i) Either "PLACE THIS CHILD RESTRAINT IN A REAR-FACING POSITION WHEN USING IT WITH AN INFANT," or "PLACE THIS INFANT RESTRAINT IN A REAR-FACING POSITION WHEN USING IT IN THE VEHICLE," and,

(ii) Either of the following statements, as appropriate, on a yellow contrasting background:

WARNING: WHEN THIS RESTRAINT IS USED IN A REAR-FACING MODE, DO NOT PLACE IN THE FRONT SEAT OF A VEHICLE THAT HAS A PASSENGER-SIDE AIR BAG.

or,

WARNING: DO NOT USE THIS INFANT RESTRAINT IN THE FRONT SEAT OF A VEHICLE THAT HAS A PASSENGER-SIDE AIR BAG.

3. In § 571.213, S5.6.1 would be amended by adding S5.6.1.8 to read as follows:

* * * * *

S5.6.1.8 In the case of each child restraint system that can be used in a rear-facing position, the instructions shall provide a warning against using rear-facing restraints at seating positions equipped with air bags, and shall explain the reasons for, and consequences of not following the warning.

Issued on April 8, 1993.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 93–8794 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–59–M

INTERSTATE COMMERCE COMMISSION

49 CFR Parts 1312 and 1314

[Ex Parte No. 444]

Electronic Filing of Tariffs

AGENCY: Interstate Commerce Commission.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Commission reopens this proceeding and requests comments on whether it should implement a data base-oriented electronic tariff filing (ETF) system that will support automated functions such as electronic data interchange (EDI) and rate analyses. Implementation of this type of ETF system, which would require the development and use of a variety of standard formats for tariff information, would permit tariff automation, and would allow the agency to process tariff filings more efficiently. The Commission also invites comments on its decision in Ex Parte No. 444 to substitute general tariff standards for many of the detailed publishing regulations previously established for printed tariffs.

DATES: Comments are due on June 15, 1993.

ADDRESSES: Send an original and 10 copies of comments to: Interstate Commerce Commission, Office of the Secretary, Case Control Branch, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: James W. Greene (202) 927–5597 or Charles E. Langyher, III (202) 927–5160 [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To obtain a copy of the full decision, write to, call or pick up in person from: Office of the Secretary, room 2215, Interstate Commerce Commission, 12th St. and Constitution Ave., NW., Washington, DC 20423. Telephone (202) 927–7428. (Assistance for the hearing impaired is available through TDD services (202) 927–5721.)

Regulatory Flexibility

Because this is not a notice of proposed rulemaking within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), we need not conduct now an examination of its impact on small business pursuant to that Act. Nevertheless, we welcome any comments regarding the small entities considerations embodied in that Act. If we decide to issue a notice of proposed rulemaking, we will conduct an appropriate Regulatory Flexibility Act examination.

Environmental Statement

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

List of Subjects

49 CFR Part 1312

Motor carriers, Moving of household goods, Pipelines, Railroads, Tariffs.

49 CFR Part 1314

Motor carriers, Railroads, Tariffs.

Decided: March 23, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden. Chairman McDonald and Vice Chairman Simmons commented with separate expressions.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9003 Filed 4–15–93; 8:45 am]

BILLING CODE 7035–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AB83

Endangered and Threatened Wildlife and Plants; Proposed Listing of Water Howellia (Howellia aquatilis) as Threatened

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule and notice of petition finding.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes threatened status for a plant, *Howellia aquatilis* (water howellia). *Howellia aquatilis* has been extirpated from historical sites in Washington and Idaho and entirely from California and Oregon. Small

populations currently are extant in Montana, Washington, and Idaho. The species is threatened by impacts from timber harvesting, encroachment by an exotic grass, development, and grazing. If made final, this proposed rule would implement Federal protection of the Endangered Species Act of 1973, as amended. Comments from the public regarding this proposed rule are sought.

DATES: Comments from all interested parties must be received by June 15, 1993. Public hearing requests must be received by June 1, 1993.

ADDRESSES: Comments and materials concerning this proposal should be sent to Kemper McMaster, Field Supervisor, U.S. Fish and Wildlife Service, Montana/Wyoming Field Office, Federal Building, 301 South Park, P.O. Box 10023, Helena, Montana 59626. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Lori Nordstrom at the above address (406–449–5225).

SUPPLEMENTARY INFORMATION:

Background

Howellia aquatilis (water howellia) comprises a monotypic genus in the family Campanulaceae (the bellflower family). *H. aquatilis* was described by Gray in 1879 from plants collected by Thomas and Joseph Howell near Portland, in Multnomah County, Oregon (Gray 1879 *in* Shelly and Mosely 1988). *H. aquatilis* is an aquatic annual that grows 10–60 cm (4–24 in) tall. Plants have extensively branched, submerged, or floating stems with narrow leaves, 1–5 cm (0.4–2 in) in length. *H. aquatilis* produces two types of flowers: Small, inconspicuous flowers beneath the water's surface and white, emergent flowers, 2–2.7 mm long (0.08–0.11 in) (adapted from Hitchock et al. 1959 and Dorn 1984 *in* Shelly and Moseley 1988). Reproduction is primarily by self-fertilization.

Presence of *H. aquatilis* appears closely correlated with the physical and climatic characteristics of its habitat (S. Shelly, U.S. Forest Service, pers. comm., 1991). *H. aquatilis* most frequently occurs in glacial pothole ponds and former river oxbows whose bottom surfaces are firm, consolidated clay and organic sediments. These wetlands are filled by spring rains and snowmelt runoff and dry out to some extent by the end of the growing season depending on temperature and precipitation. The wetland margins are usually partially surrounded by deciduous trees. Within these habitats, *H. aquatilis* is found in shallow water or around the edges of deep ponds (Shelly and Moseley 1988).

Howellia aquatilis is an annual plant, reproducing entirely from seed. Seeds of *H. aquatilis* are not capable of germinating under water. Germination only occurs if ponds dry out enough to expose the seeds to air (Lesica 1990). Therefore, the size of a colony in a particular year is directly affected by the extent to which the pond dried out in the previous growing season.

Exceedingly wet or dry seasons will have a detrimental effect on the size of a colony the following year. In wet years when ponds do not dry out, seeds do not germinate. In overly dry years, ponds may dry up, killing *H. aquatilis* plants before they are able to produce seeds. The length of time an *H. aquatilis* seed bank remains viable is unknown.

Howellia aquatilis lacks detectable genetic variation within or among populations (Lesica et al. 1988). This suggests that all populations of *H. aquatilis* represent a single, narrowly adapted genotype. This lack of detectable genetic variation correlates with the species' strict adaptation to a highly specific habitat.

Seventy-nine colonies of *H. aquatilis* are known to remain within the species' historic range. Nearly all of these colonies are clustered in two main population centers. Nineteen colonies are found in the vicinity of Spokane, Washington (18 in Spokane County and 1 in Latah County, Idaho). Fifty-nine colonies are found in the drainage of the Swan River in northwestern Montana (Lake and Missoula Counties). One isolated colony also exists near Vancouver in southwestern Washington (Clark County).

Within the two main population centers, individual colonies occur in smaller clusters of closely adjacent ponds with some outlying colonies existing. Additionally, apparently suitable yet unoccupied habitat exists within these main population centers. It is suspected that the colonies within these population centers are interdependent, acting as sources of colonists and, therefore, as protection against environmental stochasticity (S. Shelly, pers. comm., 1991).

Historically, *H. aquatilis* was known also from one site in California, four in Oregon, one additional site in Washington, and another site in Idaho (Shelly and Moseley 1988). *H. aquatilis* has not been relocated at these sites and is assumed extirpated (Shelly and Moseley 1988; S. Vrilakes, Oregon Natural Heritage Program, pers. comm., 1991).

Most of the colonies are extremely small. Of the 59 colonies in Montana, one occurs in a 12 ha (30 ac) pond, one is in a 2 ha (5 ac) pond, one is in a 1.6 ha (4 ac) pond, 4 are in 1.2 ha (3 ac) ponds, 24 are in ponds 0.4 to 0.8 ha (1 to 2 ac) in size, and the remaining 28 are in ponds of 0.4 ha (1 ac) or less (Shelly and Moseley 1988). This means that the 59 colonies in Montana occur in ponds with a maximum area of only 51 ha (127 ac). In addition, information from Montana indicates that most colonies occupy less than 100 percent of the ponds where they occur. Many colonies occupy less than 50 percent of the pond, and some occupy less than 5 percent of the area (Schassberger and Shelly 1991). This means that the 59 colonies in Montana probably occupy less than 30 ha (75 ac) of aquatic habitat. The one colony in Idaho is in a pond about 0.4 ha (1 ac) in size. Size information is available for 16 of the 19 populations in Washington. Two colonies are in a 0.8 ha (2 ac) pond, but the other 14 are in ponds of 0.4 ha (1 ac) or less (D. Naslund, Washington Natural Heritage Program, in litt., 1992).

Of the 59 known colonies of *H. aquatilis* in Montana, 21 (36 percent) are on private land, 34 (58 percent) are on land administered by the U.S. Forest Service, and 4 (7 percent) occur on private and U.S. Forest Service lands (Schassberger and Shelly 1991). In Washington, 11 of the 19 (58 percent) colonies are on private land, 7 (37 percent) are on U.S. Fish and Wildlife Service (Service) administered land, and one is on State land (D. Naslund, in litt., 1992). The single Idaho colony is on private property (R. Moseley, Idaho Natural Heritage Program, pers. comm., 1991).

In the February 21, 1990, Federal Register Notice of Review, *H. aquatilis* was reclassified from a category 2 species to a category 1 species. Shelly and Moseley (1988) recommended the reclassification for several reasons: (1) The species has been extirpated from a large portion of its previously known range, (2) it has a narrow ecological amplitude, (3) it lacks detectable inter- and intrapopulation genetic variation, and (4) habitat alteration continues in a major portion of its range. Category 1 species are those for which the Service currently has substantial information on file to support the biological appropriateness of listing as threatened or endangered. This category 1 species has a listing priority of 1, although this is now considered high after further assessment of the species' status and threats. The Service now believes a priority 4 more appropriate (see 48 FR 43098 for a description of the Service's listing priority guidelines).

As a draft proposed rule was being reviewed, on October 30, 1991, the Service was petitioned to list *H. aquatilis* as an endangered species. This proposed rule serves as evidence that substantial information is available to support that the requested action is warranted and also serves as the Service's final finding for the petitioned action.

Summary of Factors Affecting the Species

Section 4(a)(1) of the Endangered Species Act (Act) of 1973 (16 U.S.C. 1531 *et seq.*) and regulations (50 CFR part 424) promulgated to implement the listing provisions of the Act set forth the procedures for adding species to the Federal lists. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1). These factors and their application to *Howellia aquatilis* (Gray) (water howellia) are as follows:

A. The Present or Threatened Destruction, Modification, or Curtailment of its Habitat or Range

Because *H. aquatilis* has very narrow ecological requirements, even subtle changes in its habitat could be devastating to a population. It is suspected that any disturbance that alters the local surface or subsurface hydrology around the habitat may influence the colonies. By altering water quality and the composition of the wetland bottom and vegetation, some activities may affect wetland succession and the viability of *H. aquatilis* colonies. The species does not appear to be capable of colonizing disturbed habitats (Shelly and Moseley 1988). In Oregon, sites where *H. aquatilis* was historically found are now within urban developed areas. Additionally, the construction of dams along the Columbia and Willamette Rivers has led to a loss of suitable wetland habitats (Shelly and Moseley 1988). The California colony may have been eliminated by cattle grazing and trampling (Griggs and Dibble 1979). Idaho bottomland habitats have been altered by roads, development, and conversion to agriculture and pasture lands. Wetlands at Turnbull National Wildlife Refuge in Washington were altered to improve waterfowl habitat prior to concern for *H. aquatilis*. Although it is not known if *H. aquatilis* existed in these locations prior to alteration, the current presence of this species in nearby wetlands indicates that occurrence of *H. aquatilis* in altered wetlands was likely (J. Gamon, Washington Natural Heritage Program, pers. comm., 1991).

Presently, timber harvest activities occur adjacent to many wetlands occupied by *H. aquatilis*. Of the 59 colonies of *H. aquatilis* found in the Swan Valley, Montana, 22 (37 percent) occur in wetlands where logging has occurred historically or more recently around the wetland margins (Shelly and Moseley 1988). Fifty-eight percent of the colonies in Montana occur on land administered entirely by the U.S. Forest Service, and an additional 7 percent of the colonies are partially owned by the U.S. Forest Service (Schassberger and Shelly 1991). Much of the private land in Montana with populations is owned by Plum Creek Timber Company (Shelly and Moseley 1988).

Tree removal to the edges of wetlands increases the amount of sun reaching the wetland, thereby increasing water temperature and evaporation. This would increase the rate of wetland drying and, perhaps, succession rates. Wetlands adjacent to logging and public access roads are vulnerable to road improvement activities. In cases where logging has occurred near the habitat margins, an increase in siltation rate into the ponds would be expected. Such a change would probably influence both the nature of the bottom substrates and the vegetational composition of the sites. As discussed above, *H. aquatilis* occurs most frequently and most densely in ponds with firm, consolidated organic clay bottom sediments. It also is frequently found in more open areas within the ponds. Thus, increase in bottom sedimentation and subsequent competition from other vegetation could both have an adverse effect on the viability of *H. aquatilis* colonies.

Howellia aquatilis and its habitats are threatened by *Phalaris arundinacea* (reed canary grass), a highly competitive, robust grass that invades wetlands. *P. arundinacea* rapidly forms dense monocultures, causing the decline of nearly all other plants in a wetland (Apfelbaum and Sams 1987). Both native and exotic varieties of this grass occur in North America. It is not known whether the variety that occurs in wetlands within the range of *H. aquatilis* is native (Lackschewitz 1991; L. Kunze, Washington Natural Heritage Program, pers. comm., 1993; S. Shelly, pers. comm. 1993). Because of its pernicious characteristics and the lack of historical records of its presence in wetlands occupied by *H. aquatilis*, some ecologists in the Pacific northwest believe this invasive of *P. arundinacea* to be exotic (L. Kunze, pers. comm., 1993). *P. arundinacea* is present in 15 of the 19 ponds (79 percent) occupied by *H. aquatilis* in Washington. Also, it has been found in several of the Montana ponds occupied by *H. aquatilis*. *P. arundinaceae* has the potential to reduce or extirpate *H. aquatilis* if its expansion continues.

Grazing and trampling from domestic livestock physically disturbs the shoreline and vegetation. Also, trampling of the bottom sediments may adversely affect the seed bank and the consolidated substrate which appears to be necessary for vigorous germination. Additionally, livestock waste increases nutrient levels of wetlands. Two wetlands on private land in Montana with *H. aquatilis* colonies were found to be heavily impacted by grazing of domestic livestock, especially horses (Shelly and Moseley 1988).

In Washington, 75 percent of the colonies occur on private land (J. Gamon, pers. comm., 1991), and many are grazed. In Spokane County, Washington, several of the ponds containing *H. aquatilis* have been significantly altered by past and current grazing. Some of these sites possibly have been grazed by domestic livestock for 50 years or more, yet the species has persisted (B. Wiseman, Ridgefield National Wildlife Refuge, pers. comm., 1992). This suggests that the ability of *H. aquatilis* to withstand the impacts of grazing at least in the short term may depend on the timing and scale of grazing. However, the number of colonies that may have extirpated in the past as a result of grazing is unknown.

B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

There is no history of this factor being a threat to *H. aquatilis*. However, because of the interest in the species that is expected to be generated by the listing process and its taxonomically distinct status as a monotypic genus, the Service is concerned that this problem may arise in the future. To help minimize this threat, the Service has not proposed critical habitat as this action requires delineation of the species' specific habitats (see Critical Habitat section of this rule).

C. Disease of Predation

Howellia aquatilis may be subject to foraging by native wildlife. In Idaho, domestic livestock did not feed on *H. aquatilis* (Shelly and Moseley 1988). Incidence of disease is not known.

D. The Inadequacy of Existing Regulatory Mechanisms

Some protection exists for this species because it is on the U.S. Forest Service's

sensitive species list for the Pacific Northwest region. Placing a species on a sensitive species list helps control the use of the species and its habitat. Although U.S. Forest Service policy is to protect habitats of listed and sensitive species from habitat modifications or destruction and to protect individual organisms from harm or harassment as appropriate, logging continues to be a threat to colonies on U.S. Forest Service lands. Some Federal laws, such as the Clean Water Act and the Food Security Act, contain protections for wetlands; however, whether these laws are sufficient to conserve *H. aquatilis* habitat is doubtful. Thirty-four of the 79 colonies (43 percent) occur entirely on private lands where they have no protection.

E. Other Natural or Manmade Factors Affecting its Continued Existence

The lack of genetic variation between and among populations of *H. aquatilis* and its extremely specialized habitat requirements add to the vulnerability of the species. Genetic variability generally enables at least some individuals of a species to withstand environmental stress. *H. aquatilis* may be less able to adapt to environmental changes because of its lack of genetic variability (Lesica et al. 1988). As a result, the vulnerability of this species to random environmental events or habitat alteration is high.

Short- and long-term climatic changes could affect *H. aquatilis* by their potential influences on the drying patterns of the ponds. As stated previously, several years of very wet or very dry years would be expected to cause declines or even extirpations of colonies because of the germination requirements of the seeds. Long-term climatic change, such as global warming, could cause these shallow wetlands to permanently dry up, ultimately causing the species' extinction.

Succession of individual wetlands, a process in which sediment accumulates, eventually filling the depression in which water collects, resulting in a change in plant species composition, would cause the extirpation of any *H. aquatilis* colony that is present (Shelly and Moseley 1988).

The Service has carefully assessed the best scientific and commerical information available regarding the past, present, and future threats faced by this species in determining to propose this rule. Based on this evaluation, the Service proposes to list *Howellia aquatilis* (water howellia) as a threatened species. Historical records show that *H. aquatilis* has been extirpated from one-third of its global range (Shelly and Moseley 1988). Remaining *H. aquatilis* colonies are clustered in only two main areas in the northwestern United States. *H. aquatilis* lacks genetic variation between or among populations and is a habitat specialist. For these reasons it is vulnerable to both natural and man-caused habitat perturbations. For the reasons given below, it is not considered prudent to propose designation of critical habitat.

Critical Habitat

Section 4(a)(3) of the Act, as amended, requires that, to the maximum extent prudent and determinable, the Secretary proposes critical habitat at the time the species is proposed to be endangered or threatened. The Service finds that designation of critical habitat is not prudent for this species at this time. As discussed under Factor B in the "Summary of Factors Affecting the Species" section, *H. aquatilis* is vulnerable to taking. Publication of precise maps and descriptions of critical habitat in the **Federal Register** would make this plant more vulnerable to incidents of vandalism and could contribute to the decline of the species as has been documented with other listed species (e.g., *Hudsonia montana*) (N. Murdock, U.S. Fish and Wildlife Service, pers. comm., 1991). A listing of *H. aquatilis* as threatened would also publicize the rarity of this plant and, thus, could make it attractive to researchers or collectors of rare plants. Because it is a monotypic genus, it could be expected to stimulate more interest than most other species. The proper agencies have been notified of the locations and management needs of this plant. Landowners are being notified of the location and importance of protecting habitat of this species. Protection of this species' habitat will be addressed through the recovery process and through the Section 7 consultation process. The Service believes that Federal involvement in the areas where this plant occurs can be identified without the designation of critical habitat. Therefore, the Service finds that designation of critical habitat for this plant is not prudent at this time, because such designation likely would increase the degree of threat from vandalism, collecting, or other human activities.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, recovery actions, requirements for Federal protection, and prohibitions against certain activities. Recognition through listing encourages and results in conservation actions by Federal, State, and private agencies, groups, and individuals. The Act provides for possible land acquisition and cooperation with the States and requires that recovery actions be carried out for all listed species. Such actions are initiated by the Service following listing. The protection required of Federal agencies and the prohibitions against certain activities involving listed plants are discussed, in part, below.

Section 7(a) of the Act, as amended, requires Federal agencies to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal Agencies to confer informally with the Service on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. If a species is subsequently listed, section 7(a)(2) requires Federal agencies to insure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal Agency must enter into formal consultation with the Service.

Federal activities that may be affected by this proposal include, but are not limited to, timber harvesting, grazing on Federal land, road construction, and permits for placing fill in wetlands. Such Federal activities may be subject to Section 7 review.

The Act and its implementing regulations found at 50 CFR 17.71 and 17.73 set forth a series of general prohibitions and exceptions that apply to all threatened plants. All prohibitions of section 9(a)(2) of the Act, implemented by 50 CFR 17.71, apply. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to import or export, to transport in interstate or foreign commerce in the course of a commercial activity, to sell or offer for sale listed species in interstate or foreign commerce, or to remove and reduce to possession the species from areas under Federal jurisdiction. In addition, for endangered plants, the 1988 amendments (Pub. L. 100–478) to the Act prohibit the malicious damage or destruction on

Federal lands and the removal, cutting, digging up, or damaging or destroying of endangered plants in knowing violation of any State law or regulation, including State criminal trespass law. Section 4(d) of the Act allows for the provision of such protection to threatened species through regulations. This protection may apply to threatened plants once revised regulations are promulgated. Certain exceptions apply to agents of the Service and State conservation agencies. The Act and 50 CFR 17.72 also provide for the issuance of permits to carry out otherwise prohibited activities involving threatened plants under certain circumstances. The Service anticipates that few trade permits would ever be sought or issued because the species is not in cultivation or common in the wild. Requests for copies of the regulations on listed plants and inquiries regarding prohibitions and permits may be addressed to the Office of Management Authority, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, room 432, Arlington, Virginia 22203–3507 (703/358–2104).

Public Comments Solicited

The Service intends that any final action resulting from this proposal will be as accurate and as effective as possible. Therefore, comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule are hereby solicited. Comments particularly are sought concerning:

(1) Biological, commercial trade, or other relevant data concerning any threat (or lack thereof) to *H. aquatilis*;

(2) The location of any additional populations of this species and the reasons why any habitat should or should not be determined to be critical habitat as provided by Section 4 of the Act;

(3) Additional information concerning the range distribution and population size of the species; and

(4) Current or planned activities in the subject area and their possible impacts on this species.

The final decision on this proposal will take into consideration the comments and any additional information received by the Service, and such communications may lead to a final regulation that differs from this proposal.

The Act provides for a public hearing on this proposal, if requested. Requests must be received within 45 days of the date of publication of the proposal. Such requests must be made in writing and addressed to the Field Supervisor, U.S. Fish and Wildlife Service, Helena, Montana (see **ADDRESSES** section).

National Environmental Policy Act

The Service has determined that an Environmental Assessment, as defined under the authority of the National Environmental Policy Act of 1969, need not be prepared in connection with regulations adopted pursuant to section 4(a) of the Endangered Species Act of 1973, as amended. A notice outlining the Service's reasons for this determination was published in the **Federal Register** on October 25, 1983 (48 FR 49244).

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Apfelbaum, S.I. and C.E. Sams. 1987. Ecology and control of reed canary grass (*Phalaris arundinaceae* L.) Natural Areas J. 7:69–74.

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Lesica, P. 1990. Habitat requirements, germination behavior and seed bank dynamics of *Howellia aquatilis* in the Swan Valley, Montana. Unpubl. rpt. Flathead National Forest, Kalispell, Montana. 48pp.

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Schassberger, L.A. and J.S. Shelly. 1991. Update to the status review of *Howellia aquatilis*: field surveys, monitoring studies, and transplant experiments. 1990. Unpubl. rpt. U.S. Forest Service, Flathead National Forest, Kalispell, Montana. 57pp.

Shelly, J.S. and R. Moseley. 1988. Report on the conservation status of *Howellia aquatilis*, a candidate threatened species. Unpubl. rpt. Montana Natural Heritage Program, Helena, Montana. 166pp.

Author

The primary author of this proposed rule is Lori H. Nordstrom (see **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, and Transportation.

Proposed Regulation Promulgation

Accordingly, it is hereby proposed to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500, unless otherwise noted.

2. It is proposed to amend § 17.12 (h) by adding the following, in alphabetical order under the family Campanulaceae, to the list of Endangered and Threatened Plants:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Status	When listed	Critical habitat	Special rules
Scientific name	Common name					
*	*	*	*	*	*	*
Campanulaceae—Bellflower family:						
*	*	*	*	*	*	*
Howellia aquatilis	Water howellia	U.S.A. (MT, ID, WA, OR, CA)	T		NA	NA
*	*	*	*	*	*	*

Dated: April 6, 1993.

Richard N. Smith,

Director, Fish and Wildlife Service.

[FR Doc. 93–8945 Filed 4–15–93; 8:45 am]

BILLING CODE 4310–55–M

Notices

Federal Register
Vol. 58, No. 72
Friday, April 16, 1993

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Office of the Secretary

Montana Department of Fish, Wildlife and Parks Upland Game Bird Habitat Enhancement Program; Determination of Primary Purpose of Program Payments for Consideration as Excludable From Income Under Section 126 of the Internal Revenue Code of 1954

AGENCY: Office of the Secretary, USDA.
ACTION: Notice of determination.

SUMMARY: The Secretary of Agriculture has determined that all state cost-share payments (except the reimbursement for hand-reared pheasants) made to individuals by the State of Montana under the Montana Department of Fish, Wildlife and Parks Upland Game Bird Habitat Enhancement Program have been made primarily for the purpose of soil and water conservation, protecting or restoring the environment, and improving the quality of equatic and terrestrial wildlife habitat throughout Montana. This determination is made in accordance with section 126 of the Internal Revenue Code of 1954, as amended, 26 U.S.C. 126. The determination permits recipients of these cost-share payments to exclude them from gross income to the extent allowed by the Internal Revenue Service.

FOR FURTHER INFORMATION CONTACT: K.L. Cool, Director, Montana Department of Fish, Wildlife and Parks; 1420 East Sixth Avenue, Helena, Montana 59620; (406) 444–3186.

SUPPLEMENTARY INFORMATION: Section 126 of the Internal Revenue Code of 1954, as amended by the Revenue Act of 1978 and the Technical Corrections Act of 1979, 26 U.S.C. 126, provides that certain payments made to persons under state conservation programs may be excluded from the recipient's gross income for Federal income tax purposes, if the Secretary of Agriculture determines that payments are made "primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife." The Secretary of Agriculture evaluates the conservation programs on the basis of criteria set forth in 7 CFR part 14, and makes a "primary purpose" determination for the payments made under each program. Before there may be an exclusion, the Secretary of the Treasury must determine that payments made under these conservation programs do not substantially increase the annual income derived from the property benefitted by the payments.

In 1989, the 51st Montana Legislature enacted amending legislation providing earmarked upland game bird hunting revenues to be used for the purpose of enhancing upland game bird habitat throughout the state. These funds have in fact been used primarily to provide habitat for these game bird species and projects being nongame wildlife species. In addition, these "Upland Game Bird Habitat Enhancement Program (UGBHEP) projects also provide enhanced soil and water conservation, protect and restore the environment, and have resulted in establishing and reestablishing tree plantings where they have been destroyed over time by fire, grazing, or mechanical removal.

This program is set forth in Sections 87–1–246 through 87–1–250 Montana Code Annotated (M.C.A.). Section 87–1–249 further provides that the Montana Department of Fish, Wildlife and Parks shall adopt rules for the administration of the upland game bird enhancement program created in 87–1–246 through 87–1–249. These rules for operation of the program are set forth in Sections 12.9.701 through 12.9.706 Administrative Rules of Montana (A.R.M.). The purpose of Rules 12.9.701 through 12.9.706 is to establish the process wherein program cooperators may apply to the Department of Fish, Wildlife and Parks for funding to develop habitat enhancement projects. One section of the rules, 12.9.701, also provides for reimbursement for the release of hand-reared pheasants (Phasianus colchicus) onto project areas. This singular portion of the overall program does not directly constitute soil and water conservation practices, restoring or protecting the environment, improving forests, or restoring or protecting the environment, improving forests, or providing a habitat for wildlife. As a result, it is not to be included as part of this Notice of Determination.

The objectives of the Upland Game Habitat Enhancement Program are met by completion of specific habitat enhancement projects. The landowner or cooperator contracts with the Montana Department of Fish, Wildlife and Parks for cost share assistance. The program objectives are to be achieved, and cost sharing is available for planning and installing various land treatment or management measures, including planting of grasses and legumes for wildlife nesting cover, planting and maintenance of woody shrub and tree stands, installation of grazing systems to improve range condition, and providing winter food plots for wildlife.

Section 12.9.705 provides that the Department of Fish, Wildlife and Parks will compensate individuals or organizations by cost sharing the actual costs incurred for completed upland game bird habitat enhancement projects as set forth on a contract. That section further provides that the department's share, not to exceed 100% will be negotiated on an individual project basis for cost-sharing projects. Some projects have been funded entirely with department funds. In other cases, programs funded by the U.S. Department of Agriculture's Agricultural Stabilization and Conservation Service have funded upland game bird habitat enhancement projects in part. In most cases, the landowner or cooperator has cost shared a portion of the project cost either with cash or in-kind services such as labor for installation of project improvements.

As of the approximate date of preparation of this Notice of Determination, approximately 350 landowners and cooperators have participated in the Upland Game Bird Habitat Enhancement Program. None of these projects has been demonstrated to substantially increase the annual income derived from the property benefitted by the payments. The primary reason for this occurrence is that all project areas have experienced significant environmental impact, primarily from the practice of agriculture and animal husbandry,

which long preceded the initiation of the program. It is anticipated that in every case, an even longer period of repair and the land through physical improvements to the land, will be needed before the land will be capable of substantially increasing the annual income which may be derived from it.

Procedural Matters

The authorizing legislation, regulations, and operating procedures regarding the Montana Department of Fish, Wildlife and Parks Upland Game Bird Habitat Enhancement Program have been examined using the criteria set forth in 7 CFR part 14. The Department of Agriculture has concluded that the cost-share payment for implementation of best management practices under this program (not ring-necked pheasant releases) are made to eligible persons primarily for the purpose of soil and water conservation, protecting or restoring the environment, and improving the quality of wildlife habitat.

A "Record of Decision, Montana Department of Fish, Wildlife and Parks Upland Game Bird Habitat Enhancement Program, Primary Purpose Determination for Federal Tax Purpose" has been prepared and is available upon request from the Director, Land Treatment Program Division, Soil Conservation Service, P.O. Box 2890, Washington, DC 20013, or the Director of the Montana Department of Fish, Wildlife and Parks, 1420 East Sixth Avenue, Helena, Montana 59620.

Determination

As required by section 126(b) of the Internal Revenue Code of 1954, as amended, I have examined the authorizing legislation, regulations, and operating procedures regarding the Montana Department of Fish, Wildlife and Parks Upland Game Bird Habitat Enhancement Program. In accordance with the criteria set out in 7 CFR part 14, I have determined that those cost-share payments for implementation of the habitat enhancement portion of this program are primarily for the purpose of soil and water conservation, protecting or restoring the environment, and improving the quality of wildlife habitat. However, the determination of primary purpose set forth in this notice does not apply to the release of hand-reared pheasants which also qualifies for reimbursement by the Department of Fish, Wildlife and Parks under this program. Subject to further determination by the Secretary of the Treasury, that payments made under these conservation programs do not substantially increase the annual income derived from the property benefitting by these payments, this determination permits payment recipients to exclude from gross income, for Federal income tax purposes, all or part of such cost-share payments made under said program.

Signed at Washington, DC on April 1, 1993.

Mike Espy,

Secretary.

[FR Doc. 93–8854 Filed 4–15–93; 8:45 am]

BILLING CODE 3410–01–M

New York City Department of Environmental Protection, Watershed Agricultural Program; Determination of Primary Purpose of Program Payments for Consideration as Excludable From Income Under Section 126 of the Internal Revenue Code of 1954

AGENCY: Office of the Secretary, USDA.

ACTION: Notice of determination.

SUMMARY: The Secretary of Agriculture has determined that all state cost-share payments made to individuals by the New York City Department of Environmental Protection (NYCDEP) under the NYCDEP Watershed Agricultural Program have been made primarily for the purpose of soil and water conservation, protecting or restoring the environment, and improving the quality of water entering the New York City Watershed System. This determination is made in accordance with section 126 of the Internal Revenue Code of 1954, as amended, 26 U.S.C. 126. The determination permits recipients of these cost-share payments to exclude them from gross income to the extent allowed by the Internal Revenue Service.

FOR FURTHER INFORMATION CONTACT: Albert F. Appleton, Commissioner of the New York City Department of Environmental Protection, 59–17 Junction Boulevard, Corona, New York 11368.

SUPPLEMENTARY INFORMATION: Section 126 of the Internal Revenue Code of 1954, as amended by the Revenue Act of 1978 and the Technical Corrections Act of 1979, 26 U.S.C. 126, provides that certain payments made to persons under state or local conservation programs may be excluded from a recipient's gross income for Federal income tax purposes, if the Secretary of Agriculture determines that payments are made "primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife." The Secretary of Agriculture evaluates the conservation programs on the basis of criteria set forth in 7 CFR part 14, and makes a "primary purpose" determination for the payments made under each program. Before there may be an exclusion, the Secretary of the Treasury must determine that payments made under these conservation programs do not substantially increase the annual income derived from the property benefitted by the payments.

The City of New York is authorized by Article II of the New York State Public Health Law and New York City Administrative Code, Section 24–302, to promulgate regulations to protect the City's water supply. The City's surface water supply and storage system covers over 1,900 square miles, including a system of reservoirs and other water bodies in the Catskill and Delaware Watersheds, and accounts for approximately 90 percent of the City's water supply.

The NYCDEP issued a discussion draft of watershed protection regulations in 1990. In response to concerns of the farm community, government agencies, and agricultural experts that the discussion draft sections on agriculture threatened the continued viability of farms in the New York City Watersheds, and based on the belief that agriculture is a preferred land use for purposes of water quality protection, the NYCDEP withdrew the discussion draft and implemented this voluntary Watershed Agricultural Program.

The Program is designed to protect the City's water supply, while also sustaining the long-term viability of agriculture in the watersheds. It is a multi-agency effort to address agricultural point and non-point sources of pollution. The Program uses a whole farm planning/best management practices approach to watershed protection. Payments to farmers participating in the Program for which the Section 126 exclusion is sought will be made for installation of capital improvements and implementation of best management practices which further the water quality goals of the Program. The exclusion would not apply to incentive payments to farmers to be made under the Program to encourage assistance in preparation of whole farm plans and participation in demonstration field days or farm tours.

Procedural Matters

The authorizing legislation, regulations, and operating procedures regarding the New York City Watershed Agricultural Program have been examined using the criteria set forth in

7 CFR part 14. The Department of Agriculture has concluded that the cost-share payments made for installation of capital improvements and implementation of best management practices under this Program are made to provide financial assistance to eligible persons primarily for the purpose of soil and water conservation, protecting or restoring the environment, and maintaining and improving the water quality of the New York City water supply system.

A "Record of Decision, New York City Watershed Agricultural Program, Primary Purpose Determination for Federal Tax Purpose" has been prepared and is available upon request from the Director, Land Treatment Program Division, Soil Conservation Service, P.O. Box 2890, Washington, DC 20013, or the Commissioner of the New York City Department of Environmental Protection, 59–17 Junction Boulevard, Corona, New York 11368.

Determination

As required by section 126(b) of the Internal Revenue Code of 1954, as amended, I have examined the authorizing legislation, regulations, and operating procedures regarding the New York City Watershed Agricultural Program. In accordance with the criteria set out in 7 CFR part 14, I have determined that all cost-share payments for purchase and installation of capital improvements or implementation of best management practices made under this Program are primarily for the purpose of soil and water conservation, protecting or restoring the environment, and improving the water quality of the New York City water supply system. However, the determination of primary purpose does not apply to incentive payments made to farmers for assistance in preparation of whole farm plans and participation in demonstration field days or farm tours. Subject to further determination by the Secretary of the Treasury, that payments made under these conservation programs do not substantially increase the annual income derived from the property benefitting by these payments, this determination permits payment recipients to exclude from gross income, for Federal income tax purposes, all or part of such cost-share payments made under said Program.

Signed at Washington, DC on April 1, 1993.

Mike Espy,

Secretary.

[FR Doc. 93–8853 Filed 4–15–93; 8:45 am]

BILLING CODE 3410–01–M

Oregon Oil Heat Commission's Environmental Protection Fund Program as Excludable From Income Under Section 126 of the Internal Revenue Code of 1954

AGENCY: Office of the Secretary, USDA.

ACTION: Notice of determination.

SUMMARY: The Secretary of Agriculture has determined that all payments made to individuals by the State of Oregon under the Oregon Oil Heat Commission have been made primarily for the purpose of soil and water conservation, protecting or restoring the environment, and improving the quality of the environment for Oregon. This determination is made in accordance with Section 126 of the Internal Revenue Code of 1954, as amended, 26 U.S.C. 126. The determination permits recipients of these payments to exclude them from gross income to the extent allowed by the Internal Revenue Service.

FOR FURTHER INFORMATION CONTACT: Terrie J. Heer, Administrator for the Oregon Oil Heat Commission, 1300 SE Gideon St., Portland, Oregon 97202–2419, (503) 731–3002.

SUPPLEMENTARY INFORMATION: Section 126 of the Internal Revenue Code of 1954, as amended by the Revenue Act of 1978 and the Technical Corrections Act of 1979, 26 U.S.C. 126, provides that certain payments made to persons under state restoration or protecting the environment programs may be excluded from the recipient's gross income for Federal Income tax purposes, if the Secretary of Agriculture determines that payments are made "primarily for the purpose of soil and water conservation, protecting or restoring the environment, improving forests, or providing a habitat for wildlife." The Secretary of Agriculture evaluates the conservation programs on the basis of criteria set forth in 7 CFR part 14, and makes a "primary purpose" determination for the payments made under each program. Before there may be an exclusion, the Secretary of the Treasury must determine that payments made under these conservation programs do not substantially increase the annual income derived from the property benefit by the payments.

The Oregon Oil Heat Commission was created by the 1989 Legislature. This landmark legislation established a national precedent for which Oregon has earned nationwide recognition. The Commission has two vital programs: The Education and Conservation Program and the Environmental Protection Program. Through the Education and Conservation Program, consumers receive information about efficient use of oil heat, low income fuel assistance and low income furnace rebate programs, and technical training. The Environmental Protection Program protects health and safety of the public through providing financial assistance in cost of remedial action of tank releases. To date, the Commission has funded over 240 claims with a total of $1.4 million dollars.

The cost of the Environmental Protection Fund claims can range from $900 to $97,000 and average about $8,000 a claim. Such costs would impose severe economic hardship on families and small businesses who heat with oil and are financially responsible under state and federal law. Oregonians have financial assistance to meet such obligations through the Oregon Oil Heat Commission. Without this funding, major cleanups could cause the property owner the risk of losing their homes and harm the environment.

The program is set forth in Oregon Revised Statutes 469.228 to 469.298 and Oregon Administrative Rules 130–15–020 to 130–15–150.

Procedural Matters

The authorizing legislation, regulation, and operating procedures regarding the Oregon Oil Heat Commission's Environmental Protection Fund Program have been examined using the criteria set forth on 7 CFR part 14. The Department of Agriculture has concluded that the payments made for the remedial action cleanups of heating oil tanks are made to provide financial assistance to eligible persons primarily for the purpose of soil and water conservation, protecting or restoring the environment and improving the quality of the environment in Oregon. A "Record of Decision, Oregon Oil Heat Commission Environmental Protection Fund Program, Primary Purpose Determination for Federal Tax Purpose" has been prepared and is available upon request from the Administrator, Oregon Oil Heat Commission, 1300 SE Gideon St., Portland, Oregon 97202–2419.

Determination

As required by section 126(b) of the Internal Revenue Code of 1954, as amended I have examined the authorizing legislation, regulations, and operating procedures the Oregon Oil Heat Commission's Environmental Protection Fund Program. In accordance with the criteria set out in 7 CFR part 14, I have determined that all payments for remedial action for cleanup of heating oil tank releases made under this program are primarily for the purpose of soil and water conservation,

protecting or restoring the environment, and improving the quality of the environment for the State of Oregon. Subject to further determination by the Secretary of the Treasury, this determination permits payment recipients to exclude from gross income, for Federal income tax purposes, all or part of such payments made under said program.

Signed at Washington, DC on April 1, 1993

Mike Espy,

Secretary.

[FR Doc. 93–8852 Filed 4–15–93; 8:45 am]

BILLING CODE 3410-01-M

Animal and Plant Health Inspection Service

[Docket No. 93–045–1]

Availability of Environmental Assessments and Findings of No Significant Impact Relative to Issuance of Permits To Field Test Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that six environmental assessments and findings of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of permits to allow the field testing of genetically engineered organisms. The environmental assessments provide a basis for our conclusion that the field testing of these genetically engineered organisms will not present a risk of introducing or disseminating a plant pest and will not have a significant impact on the quality of the human environment. Based on its findings of no significant impact, the Animal and Plant Health Inspection Service has determined that environmental impact statements need not be prepared.

ADDRESSES: Copies of the environmental assessments and findings of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect those documents are encouraged to call ahead on (202) 690–2817 to facilitate entry into the reading room.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, BBEP, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7612. For copies of the environmental assessments and findings of no significant impact, write to Mr. Clayton Givens at the same address. Please refer to the permit numbers listed below when ordering documents.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 (referred to below as the regulations) regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article may be introduced into the United States. The regulations set forth the procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

In the course of reviewing each permit application, APHIS assessed the impact on the environment that releasing the organisms under the conditions described in the permit application would have. APHIS has issued permits for the field testing of the organisms listed below after concluding that the organisms will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment. The environmental assessments and findings of no significant impact, which are based on data submitted by the applicants and on a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field tests.

Environmental assessments and findings of no significant impact have been prepared by APHIS relative to the issuance of permits to allow the field testing of the following genetically engineered organisms:

Permit No.	Permittee	Date issued	Organisms	Field test location
93–026–09, renewal of permit 91–156–01, issued on 08–29–91.	University of Florida	03–24–93	Tobacco plants genetically engineered to express resistance to tobacco etch virus.	Florida.
93–004–02, renewal of permit 90–351–01, issued on 03–15–91.	U.S. Department of Agriculture, Agricultural Research Service.	03–26–93	Walnut trees genetically engineered to express a delta-endotoxin from *Bacillus thuringiensis* subsp. *kurstaki* for resistance to lepidop- teran insects.	California.
93–012–06, renewal of permit 92–037–03, issued on 05–19–92.	Monsanto Agricultural Company.	03–26–93	Soybean plants genetically engineered to express tolerance to the phosphinothricin class of herbicides.	Wisconsin.
93–019–03, renewal of permit 92–014–01, issued on 04–29–92.	North Carolina State University.	03–26–93	Tobacco plants genetically engineered to express a delta-endotoxin from *Bacillus thuringiensis* subsp. *kurstaki* strain HD1 for resistance to lepidopteran insects.	North Carolina.
93–026–07, renewal of permit 92–002–03, issued on 04–16–92.	Pioneer Hi-Bred International, Incorporated.	03–26–93	Corn plants genetically engineered to express resistance to maize chlorotic dwarf virus.	Tennessee.
93–027–01, renewal of permit 92–028–01, issued on 05–27–92.	Purdue University	03–26–93	Tomato plants genetically engineered to express an anti-sense pectin methylesterase chimeric gene to increase the soluble solid content.	Indiana.

The environmental assessments and findings of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1508), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381–50384, August 28, 1979, and 44 FR 51272–51274, August 31, 1979).

Done in Washington, DC, this 13th day of April 1993

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93–8949 Filed 4–15–93; 8:45 am]

BILLING CODE 3410–34–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERLY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List a military resale commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: May 17, 1993.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Square 3, suite 403, 1735 Jefferson Davis Highway, Arlington, Virginia 22202–3461.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the military resale commodity and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the military resale commodity and services to the Government.

2. The action does not appear to have a severe adverse impact on the current contractors for the military resale commodity and services.

3 The action will result in authorizing small entities to furnish the military resale commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the military resale commodity and services proposed for addition to the Procurement List.

Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

It is proposed to add the following military resale commodity and services to the Procurement List for production by the nonprofit agency listed:

Military Resale Commodity

Cutlery, Plastic
M.R. 581
Nonprofit Agency: Royal Maid Association for the Blind, Inc., Hazlehurst, Mississippi

Services

Janitorial/Custodial
Salmon National Forest Supervisor's Office
Highway 93 South
Salmon, Idaho
Nonprofit Agency: Development Workshop, Inc., Idaho Falls, Idaho

Janitorial/Custodial
Naval Intelligence Command
Building #1 (NIC–1)
Suitland, Maryland
Nonprofit Agency: Melwood Horticultural Training Center, Upper Marlboro, Maryland

Janitorial/Custodial
Moorhead Federal Building
Pittsburgh, Pennsylvania
Nonprofit Agency: Goodwill Industries of Pittsburgh, Inc., Pittsburgh, Pennsylvania

Janitorial/Custodial
Post Office and Courthouse
Alexandria, Virginia
Nonprofit Agency: Melwood Horticultural Training Center, Upper Marlboro, Maryland.

Beverly L. Milkman,

Executive Director.

[FR Doc. 93–8966 Filed 4–15–93; 8:45 am]

BILLING CODE 6820–33–P

DEPARTMENT OF DEFENSE

Department of the Army

Armed Forces Epidemiological Board; Open Meeting

AGENCY: Armed Forces Epidemiological Board, DoD.

ACTION: Notice of open meeting.

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–462) announcement is made of the following committee meeting:

Name of the committee: Armed Forces Epidemiological Board.
Date of the Meeting: June 3–4, 1993.
Time: 0800–1600.
Place: Holiday Inn, San Antonio, Texas.
Proposed Agenda: 3–4 Jun3 1993—Service preventive medicine reports and current infectious disease concerns.

This meeting will be open to the public but limited by space accommodations. Any interested person may attend, appear before or file statements with the committee at the time and in the manner permitted by the committee. Interested persons wishing to participate should advise the Executive Secretary, AFEB, Skyline Six, 5109 Leesburg Pike, room 667, Falls Church, Virginia 22041–3258.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 93–8900 Filed 4–15–93; 8:45 am]

BILLING CODE 3710–08–M

Modify the Personal Property Traffic Management Regulation, DoD 4500.34–R; Modification of Procedures Concerning Approval for Use of Foreign Flag Ocean and/or Air Carriers to Move DoD-Sponsored International Household Goods and Unaccompanied Baggage Shipments

AGENCY: Military Traffic Management Command, DoD.

ACTION: Notice.

SUMMARY: Reference 57 FR 7572, Modification of DoD Regulation 4500.34–R, appendix A, Tender of Service, part B, International, subpart 33. Overseas Shipments. Changes to the Military Sealift Command procedures of the foreign flag approval process will be

implemented April 15, 1993. All current DoD-approved international through Government Bill of Lading carriers will be mailed an updated copy of the procedures. In addition, the revised International Personal Property Rate Solicitation I–2, will include all changes. Copies of the change can be obtained by contacting ADCSOPS-Transportation Services, Negotiations Division, Installation Branch, Military Traffic Management Command, 5611 Columbia Pike, Falls Church, VA 22041–5050.

DATES: (Implementation and effective date of the modification is April 15, 1993.)

FOR FURTHER INFORMATION CONTACT: Mr. Chuck Borum, Headquarters, Military Traffic Management Command, ATTN: MTOP–T–IN, 5611 Columbia Pike, Falls Church, VA 22041–5050, (703) 756–2383.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 93–8899 Filed 4–15–93; 8:45 am]

BILLING CODE 3710-08-M

Patent Application Available for Licensing

ACTION: Notice of availability.

AGENCY: U.S. Army Judge Advocate General, DoD.

SUMMARY: In accordance with 37 CFR 404.6, announcement is made of the availability of the following U.S. patent for non-exclusive, exclusive or partially exclusive licensing. This patent has been as signed to the United States of America as represented by the Secretary of the Army, Washington, DC.

U.S. Patent Application SN 07/982,446 filed 23 November 1992, "Rapidly Deployable Volume-Displacement System for Restraining Movement of Objects."

FOR FURTHER INFORMATION CONTACT:

U.S. Army Armament, Research, Development and Engineering Center, ATTN: SMCAR–GCL (Edward Goldberg), Picatinny Arsenal, New Jersey 07806–5000.

Kenneth L. Denton,

Army Federal Register Liaison Officer.

[FR Doc. 93–8898 Filed 4–15–93; 8:45 am]

BILLING CODE 3710-08-M

Department of the Army

Corps of Engineers

Wetland Delineator Certification Program—Training

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Notice.

SUMMARY: The purpose of this notice is to announce the availability of training materials developed in conjunction with the Corps Wetland Delineator Certification Program (WDCP). The WDCP is being developed in accordance with section 307(e) of the Water Resources Development Act of 1990 (WRDA 90), as previously announced in the **Federal Register** December 30, 1992 (57 FR 62312). A working draft of the training materials will be available this spring. This package has been developed for those who intend to provide wetland delineation training. The Corps intends to provide a list of potential sources for this training to individuals who wish to receive wetland delineation training for the WDCP. If you want to be on this list of wetland delineation training sources, contact the Wetlands Research and Technology Center of the Corps Waterways Experiment Station (WES). This list will be provided to Corps districts nationwide for dissemination to the public.

FOR FURTHER INFORMATION CONTACT: To request a copy of the draft training materials, and/or to be included on the list of trainers of this material, contact the WES, Wetlands Research and Technology Center, 3909 Halls Ferry Road, Vicksburg, Mississippi 39180–6199, (601) 634–4217, FAX: (601) 634–3664. For information on the WDCP, contact Ms. Karen Kochenbach, Office of the Chief of Engineers, Attn: CECW–OR, 20 Massachusetts Avenue NW., Washington, DC 20314–1000, (202) 272–0199.

SUPPLEMENTARY INFORMATION: Section 307(e) of WRDA 90 authorizes the Secretary of the Army to establish a program for the training and certification of individuals as wetland delineators, and to carry out demonstration projects in districts of the Corps. The WDCP demonstration projects began March 1, 1993, in the States of Washington, Maryland, and Florida, administered by the Seattle, Baltimore, and Jacksonville Districts, respectively. For information on the demonstration project in the State of Washington, contact the U.S. Army Corps of Engineers, Seattle District, ATTN: CENPS–EN–PL–ER, P.O. Box 3755, Seattle, WA 98124–2255, or call Ms. Kathy Kunz, (206) 764–3624; in Maryland, contact the U.S. Army Corps of Engineers, Baltimore District, ATTN: CENAB–OP–RX, P.O. Box 1715, Baltimore, MD 21203–1715, or call Mrs. Deborah Nizer, (410) 962–1843; in Florida, contact the U.S. Army Corps of Engineers, Jacksonville District, ATTN: CESAJ–RD, P.O. Box 4970, Jacksonville, FL 32232–0019, or call Mr. Ron Silver, (904) 232–2502. Nationwide implementation of the final WDCP is anticipated to begin in March of 1994, at which time the demonstration projects will end. The Corps intends to issue a proposed rule on the WDCP prior to nationwide implementation.

Corps certification of wetland delineators indicates that an individual has successfully demonstrated the capability to perform satisfactory wetland delineations, consistent with the 1987 Corps of Engineers Wetland Delineation Manual (Waterways Experiment Station Technical Report Y–87–1, January, 1987) (1987 Manual) and supplemental guidance. Although certification does not guarantee that future delineations submitted to the Corps by certified delineators will be approved, delineations performed by certified delineators will take less time for the Corps to verify. The Corps districts will exercise final decision-making authority regarding acceptance of wetland delineations performed by certified delineators.

Copies of the 1987 Manual are available from the National Technical Information Service, 5285 Port Royal Road, Attn: Order Department, Springfield, Virginia 22171, Document #ADA 176 734. Copies of the supplemental guidance issued by the Corps concerning use of the 1987 Manual, which includes the October 7, 1991, Questions and Answers, and the March 6, 1992, Clarification and Interpretation memoranda, may be obtained by contacting the Regulatory Branch of your local Corps district or the Office of the Chief of Engineers, (202) 272–0199.

Training in the 1987 Manual will be a prerequisite for all WDCP applicants (i.e., individuals who apply to districts to be certified) after the demonstration projects (i.e., March 1994). The prerequisite training, as well as the requirement that all training be conducted with a certified delineator present, is waived during the demonstration phase of the WDCP. Although participation in the demonstration projects is open to all, it is unlikely that individuals lacking training and experience in the 1987 Manual will be able to demonstrate that

they meet the minimum standards to be provisionally certified during the demonstration projects.

In order to meet the prerequisite for training in the future, individuals may prepare during the demonstration program by *one* of the following means:

(1) Acquisition of a provisional certification from the Baltimore, Seattle or Jacksonville Districts; or

(2) Obtaining training in Corps 1987 Wetland Delineation Manual based on the Corps training materials. A certification of successful completion of this training will be issued by the training source and required by the Corps.

If you feel you have had appropriate training, it is recommended that you take advantage of the waiver during the demonstration projects and successfully complete WDCP provisional certification. Once the WDCP is implemented nationwide, no exceptions or equivalencies to the training prerequisites, nor requests of that nature, will be accepted.

Approved:

John P. Elmore,

Chief, Operations, Construction and Readiness Division, Directorate of Civil Works.

[FR Doc. 93–8902 Filed 4–15–93; 8:45 am]

BILLING CODE 3710-92-M

DEPARTMENT OF ENERGY

Pittsburgh Energy Technology Center; Noncompetitive Financial Assistance Award

AGENCY: Bartlesville Project Office and the Pittsburgh Energy Technology Center, U.S. Department of Energy.

ACTION: Acceptance of a Determination of Noncompetitive Financial Assistance award with the Society of Petroleum Engineers.

SUMMARY: The Department of Energy (DOE), Bartlesville Project Office announces that pursuant to 10 CFR 600.07(b)(2)(i) criteria (B) and (D), it intends make a noncompetitive financial assistance (grant) award through the Pittsburgh Energy Technology Center to the Society of Petroleum Engineers for a research effort entitled "Colloquim Petroleum Engineering Education."

ADDRESSES: Department of Energy, Pittsburgh Energy Technology Center, Acquisition and Assistance Division, P.O. Box 10940, MS 921–118, Pittsburgh, PA 15236.

FOR FURTHER INFORMATION CONTACT: Cynthia Y. Mitchell, Contract Specialist, (412) 892–4862.

SUPPLEMENTARY INFORMATION:

Grant Number: DE–FG22–93BC14877.

Title of Research Effort: "Colloquium on Petroleum Engineering Education."

Awardee: Society on Petroleum Engineering Education.

Term of Assistance Effort: Twelve (12) months.

Grant Estimated Total Value: $20,000.

Objective: Based upon the authority of 10 CFR 600.07(b)(2)(i) criteria (B) and (D), the objective of this grant is to permit the Department of Energy (DOE) Bartlesville Project Office (BPO) and the Society of Petroleum Engineers to participate in funding a workshop to consider major topics relating to the changing petroleum industry, considered by teams of participants under the guidance of selected group leaders. The colloquium is a prime opportunity for DOE to see that the perspective of government oil recovery research is included in the educational and industrial activities that train and utilize petroleum engineers. This includes DOE's recent initiative to enhance the petroleum engineer's understanding of geological and geophysical aspects of reservoirs as a means of increasing the efficiency of oil and gas recovery processes.

Dated: March 31, 1993.

Dale A. Siciliano,

Contracting Officer.

[FR Doc. 93–8969 Filed 4–15–93; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Project No. 2509–001, Virginia]

The Potomac Edison Co.; Availability of Environmental Assessment

April 12, 1993.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for a subsequent license for the existing Shenandoah Hydro Station Project, located on the South Fork Shenandoah River in Page County, Virginia, in the town of Shenandoah, and has prepared an Environmental Assessment (EA) for the project. In the EA, the Commission's staff has analyzed the existing and potential future environmental impacts of the project and has concluded that approval of the project would not constitute a major federal action that would significantly affect quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, room 3104, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8917 Filed 4–15–93; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2391–001 Virginia]

The Potomac Edison Co.; Availability of Environmental Assessment

April 12, 1993.

In accordance with the National Environmental Policy Act of 1969 and the Federal Energy Regulatory Commission's (Commission's) regulations, 18 CFR part 380 (Order No. 486, 52 FR 47897), the Office of Hydropower Licensing has reviewed the application for a subsequent license for the existing Warren Hydro Station Project, located on the Shenandoah River in Warren County, Virginia, near the town of Front Royal, and has prepared an Environmental Assessment (EA) for the project. In the EA, the Commission's staff has analyzed the existing and potential future environmental impacts of the project and has concluded that approval of the project would not constitute a major federal action that would significantly affect quality of the human environment.

Copies of the EA are available for review in the Public Reference Branch, room 3104, of the Commission's offices at 941 North Capitol Street, NE., Washington, DC 20426.

Lois D. Cashell,

Secretary

[FR Doc. 93–8916 Filed 4–15–93; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ST93–2455–000 through ST93–2802–000]

Iroquois Gas Trans. System L.P.; Self-Implementing Transactions

April 9, 1993.

Take notice that the following transactions have been reported to the Commission as being implemented pursuant to part 284 of the Commission's regulations, sections 311 and 312 of the Natural Gas Policy Act of 1978 (NGPA), section 7 of the NGA

and section 5 of the Outer Continental Shelf Lands Act.[1]

The "Recipient" column in the following table indicates the entity receiving or purchasing the natural gas in each transaction.

The "Part 284 Subpart" column in the following table indicates the type of transaction.

A "B" indicates transportation by an interstate pipeline on behalf of an intrastate pipeline or a local distribution company pursuant to § 284.102 of the Commission's regulations and section 311(a)(1) of the NGPA.

A "C" indicates transportation by an intrastate pipeline on behalf of an interstate pipeline or a local distribution company served by an interstate pipeline pursuant to § 284.122 of the Commission's regulations and section 311(a)(2) of the NGPA.

A "D" indicates a sale by an intrastate pipeline to an interstate pipeline or a local distribution company served by an interstate pipeline pursuant to § 284.142 of the Commission's Regulations and section 311(b) of the NGPA. Any interested person may file a complaint concerning such sales pursuant to § 284.147(d) of the Commission's Regulations.

An "E" indicates an assignment by an intrastate pipeline to any interstate pipeline or local distribution company pursuant to § 284.163 of the Commission's regulations and section 312 of the NGPA.

A "G" indicates transportation by an interstate pipeline on behalf of another interstate pipeline pursuant to § 284.222 and a blanket certificate issued under § 284.221 of the Commission's regulations.

A "G–I" indicates transportation by an intrastate pipeline company pursuant to a blanket certificate issued under § 284.227 of the Commission's regulations.

A "G–S" indicates transportation by interstate pipelines on behalf of shippers other than interstate pipelines pursuant to § 284.223 and a blanket certificate issued under § 284.221 of the Commission's regulations.

A "G–LT" or "G–LS" indicates transportation, sales or assignments by a local distribution company on behalf of or to an interstate pipeline or local distribution company pursuant to a blanket certificate issued under § 284.224 of the Commission's regulations.

A "G–HT" or "G–HS" indicates transportation, sales or assignments by a Hinshaw Pipeline pursuant to a blanket certificate issued under § 284.224 of the Commission's regulations.

A "K" indicates transportation of natural gas on the Outer Continental Shelf by an interstate pipeline on behalf of another interstate pipeline pursuant to § 284.303 of the Commission's regulations.

A "K–S" indicates transportation of natural gas on the Outer Continental Shelf by an interstate pipeline on behalf of shippers other than interstate pipelines pursuant to § 284.303 of the Commission's regulations.

Lois D. Cashell,

Secretary.

[1] Notice of a transaction does not constitute a determination that the terms and conditions of the proposed service will be approved or that the noticed filing is in compliance with the Commission's regulations.

Docket No.*	Transporter/seller	Recipient	Date filed	Part 284 subpart	Est. Max. daily quantity**	AFF. Y/A/N***	Rate sch.	Date commenced	Projected termination date
ST93–2455	Iroquois Gas Trans. System, L.P.	Brooklyn Union Gas Co	02–01–93	B	210,000	Y	I	01–01–93	Indef.
ST93–2456	Iroquois Gas Trans. System, L.P.	Continental Energy Marketing, Inc.	02–01–93	G–S	20,000	N	F	01–06–93	02–01–93
ST93–2457	Iroquois Gas Trans. System, L.P.	Power City Partners, L.P	02–01–93	G–S	30,000	N	I	12–24–92	Indef.
ST93–2458	Iroquois Gas Trans. System, L.P.	Orchard Gas Corp	02–01–93	G–S	550,000	Y	I	01–01–93	Indef.
ST93–2459	Dow Pipeline Co	Tennessee Gas Pipeline Co.	02–01–93	C	30,000	N	I	01–01–93	12–01–94
ST93–2460	Channel Industries Gas Co.	ANR Pipeline Co	02–01–93	C	70,000	N	I	01–01–93	Indef.
ST93–2461	Northern Natural Gas Co	Fremont Department of Utilities.	02–01–93	B	3,000	N	F	11–01–92	Indef.
ST93–2462	Northern Natural Gas Co	City of Sac City	02–01–93	G–S	893	N	F	12–01–92	Indef.
ST93–2463	Northern Natural Gas Co	City of Ponca	02–01–93	G–S	300	N	F	11–01–92	Indef.
ST93–2464	Northern Natural Gas Co	City of Gilmore	02–01–93	G–S	163	N	F	11–01–92	Indef.
ST93–2465	Northern Natural Gas Co	City of Brooklyn	02–01–93	G–S	283	N	F	11–01–92	Indef.
ST93–2466	Northern Natural Gas Co	City of Waukee	02–01–93	G–S	418	N	F	11–01–92	Indef.
ST93–2467	Northern Natural Gas Co	City of New Ulm	02–01–93	B	2,540	N	F	11–01–92	Indef.
ST93–2468	Northern Natural Gas Co	Lake Park Municipal Utilities.	02–01–93	G–S	270	N	F	11–01–92	Indef.
ST93–2469	Northern Natural Gas Co	City of Coon Rapids	02–01–93	B	258	N	F	11–01–92	Indef.
ST93–2470	Northern Natural Gas Co	Osage Municipal Utilities	02–01–93	G–S	450	N	F	11–01–92	Indef.
ST93–2471	Northern Natural Gas Co	City of Two Harbors	02–01–93	G–S	250	N	F	11–01–92	Indef.
ST93–2472	Northern Natural Gas Co	City of Sabula	02–01–93	G–S	208	N	F	11–01–92	Indef.
ST93–2473	Northern Natural Gas Co	City of Duluth	02–01–93	G–S	1,000	N	F	11–01–92	Indef.
ST93–2474	Northern Natural Gas Co	City of Duluth	02–01–93	G–S	7,000	N	F	11–01–92	Indef.
ST93–2475	Sabin Pipe Line Co	Exxon Corp	02–01–93	G–S	75,000	N	I	01–07–93	Indef.
ST93–2476	Tennessee Gas Pipeline Co.	National Fuel Gas Supply Corp.	02–01–93	G–S	200,000	N	I	01–01–93	Indef.
ST93–2477	Tennessee Gas Pipeline Co.	Tenngasco Corp	02–01–93	G–S	1,000,000	A	I	12–31–92	Indef.
ST93–2478	Tennessee Gas Pipeline Co.	Granite State Gas Trans., Inc.	02–01–93	G	1,000,000	A	I	12–31–92	Indef.
ST93–2479	Tennessee Gas Pipeline Co.	Tenngasco Corp	02–01–93	G–S	2,000,000	A	I	12–31–92	Indef.
ST93–2480	Tennessee Gas Pipeline Co.	National Fuel Gas Supply	02–01–93	G	1,000,000	A	I	01–01–93	Indef.
ST93–2481	Tennessee Gas Pipeline Co.	CNG Transmission Corp	02–01–93	G	1,000,000	A	I	01–01–93	Indef.
ST93–2482	Trunkline Gas Co	Yuma Gas Corp	02–01–93	G–S	600	N	F	01–16–93	Indef.
ST93–2483	Colorado Interstate Gas Co.	Wyoming Gas Co	02–01–93	B	350	N	F	01–01–93	01–31–95
ST93–2484	Transcontinental Gas P/L Corp.	Seagull Marketing Services, Inc.	02–01–93	G–S	860,000	N	I	01–25–93	Indef.
ST93–2485	Transcontinental Gas P/L Corp.	NGC Transportation, Inc	02–01–93	G–S	4,860,000	N	I	01–07–93	Indef.
ST93–2486	Transcontinental Gas P/L Corp.	CNG Trading Co	02–01–93	G–S	120,000	N	I	01–22–93	Indef.
ST93–2487	Natural Gas P/L Co. of America.	ONG Western, Inc	02–01–93	B	100,000	N	I	01–20–93	Indef.
ST93–2488	Natural Gas P/L Co. of America.	Associated Natural Gas, Inc.	02–01–93	G–S	2,000	N	F	01–01–93	02–28–93

Docket No.*	Transporter/seller	Recipient	Date filed	Part 284 subpart	Est. Max. daily quantity**	AFF. Y/A/N***	Rate sch.	Date commenced	Projected termination date
ST93–2489	Questar Pipeline Co	Kern River Gas Trans., et al.	02–01–93	G	200,000	N	I	01–01–93	Indef.
ST93–2490	Questar Pipeline Co	CNG Producing Co	02–01–93	G–S	10,000	N	F	01–01–93	05–31–07
ST93–2491	Tennessee Gas Pipeline Co.	Tenngasco Corp	02–01–93	G–S	1,000,000	A	I	12–31–93	Indef.
ST93–2492	Columbia Gas Transmission Corp.	ONEXXX Production Exploration Corp.	02–01–93	G–S	25,000	N	F	01–01–93	02–28–93
ST93–2493	Columbia Gas Transmission Corp.	Columbia Gas Development Corp.	02–01–93	G–S	1,100	Y	F	01–01–93	03–31–93
ST93–2494	CNG Transmission Corp	Alcan Rolled Products	02–01–93	G–S	7,000	N	I	01–01–93	Indef.
ST93–2495	CNG Transmission Corp	IESCO	02–01–93	G–S	10,000	N	I	01–21–93	Indef.
ST93–2496	CNG Transmission Corp	Alcan Rolled Products	02–01–93	G–S	7,000	N	I	01–01–93	Indef.
ST93–2497	CNG Transmission Corp	Gas Access Systems	02–01–93	G–S	700	N	I	01–15–93	Indef.
ST93–2498	CNG Transmission Corp	O & R Energy	02–01–93	G–S	3,650	N	I	01–14–93	Indef.
ST93–2499	CNG Transmission Corp	IDECT OSWEGO	02–01–93	G–S	3,000	N	I	01–21–93	Indef.
ST93–2500	Equitrans, Inc	Transport Gas Corp	02–01–93	G–S	40,483	N	I	11–02–92	Indef.
ST93–2501	Channel Industries Gas Co.	Amoco Gas Co	02–01–93	C	20,000	N	I	01–01–93	Indef.
ST93–2502	Delhi Gas Pipeline Corp	El Paso Natural Gas Co., et al.	02–01–93	C	15,000	N	I	01–01–93	Indef.
ST93–2503	Questar Pipeline Co	Colorado Interstate Gas Co., et al.	02–01–93	B	200,000	N	I	01–22–93	Indef.
ST93–2504	ANR Pipeline Co	Interstate Gas Marketing, Inc.	02–02–93	G–S	200	N	F	01–15–93	01–14–94
ST93–2505	Colorado Interstate Gas Co.	Montana Power Co	02–02–93	B	32,000	A	I	12–01–92	Indef.
ST93–2506	Colorado Interstate Gas Co.	NGC Transportation, Inc	02–02–93	G–S	50,000	N	I	01–21–93	Indef.
ST93–2507	Colorado Interstate Gas Co.	Interenergy Transmission Partners.	02–02–93	G–S	20,000	N	I	01–09–93	Indef.
ST93–2508	Arkla Energy Resources	Ross Explorations Inc	02–02–93	G–S	1,000	N	I	12–01–92	Indef.
ST93–2509	Arkla Energy Resources	Alumax Mill Products, Inc	02–02–93	G–S	3,200	A	F	12–01–92	Indef.
ST93–2510	Arkla Energy Resources	Sonat Marketing Co	02–02–93	G–S	85,000	N	I	12–01–92	Indef.
ST93–2511	Arkla Energy Resources	Enmark Gas Corp	02–02–93	G–S	15,000	N	I	12–01–92	Indef.
ST93–2512	Arkla Energy Resources	Tidewest Trading & Transport Co.	02–02–93	G–S	100,000	N	I	12–01–92	Indef.
ST93–2513	Arkla Energy Resources	ONG Transmission Co	02–02–93	B	1,440	N	I	12–01–92	Indef.
ST93–2514	Columbia Gas Transmission Corp.	North Atlantic Utilities, Inc	02–02–93	G–S	16,200	Y	I	02–01–93	Indef.
ST93–2515	Columbia Gas Transmission Corp.	Columbia Gas of Ohio, Inc.	02–02–93	B	860	Y	F	02–01–93	Indef.
ST93–2516	Columbia Gas Transmission Corp.	Pennsylvania Gas and Water Co.	02–02–93	B	9,737	Y	F	02–01–93	Indef.
ST93–2517	Columbia Gas Transmission Corp.	Mountaineer Gas Co	02–02–93	B	3,000	N	I	02–01–93	Indef.
ST93–2518	Columbia Gas Transmission Corp.	Virginia Natural Gas	02–02–93	B	6,000	Y	I	02–01–93	Indef.
ST93–2519	Columbia Gas Transmission Corp.	Columbia Gas of Ohio, Inc.	02–02–93	B	550	Y	F	02–01–93	Indef.
ST93–2520	Columbia Gas Transmission Corp.	Columbia Gas of Ohio, Inc.	02–02–93	B	39,040	Y	F	02–01–93	Indef.
ST93–2521	Columbia Gas Transmission Corp.	Columbia Gas of Kentucky, Inc.	02–02–93	B	20,014	Y	F	02–01–93	Indef.

ST93–2522	Columbia Gas Transmission Corp.	Columbia Gas of Ohio, Inc.	02–02–93	B	2,000	A	F	02–01–93	Indef.
ST93–2523	Columbia Gas Transmission Corp.	Columbia Gas of Ohio, Inc.	02–02–93	B	683	Y	F	02–01–93	Indef.
ST93–2524	Colorado Interstate Gas Co.	Montana Power co	02–03–93	B	32,000	A	I	12–01–92	Indef.
ST93–2525	Tennessee gas Pipeline Co.	Alatenn Energy Marketing Co.	02–03–93	G–S	12,000	N	F	01–05–93	Indef.
ST93–2526	Northern Natural Gas Co .	Associate Natural Gas, Inc.	02–03–93	B	50,000	N	I	12–12–92	Indef.
ST93–2527	Enercorp Pipeline Ltd	Texas Eastern Transmission Corp.	02–03–93	C	30,000	N	I	01–01–93	Indef.
ST93–2528	Columbia Gas Transmission Corp.	W.E. Brewer, Agent	02–03–93	G–S	1,138	N	F	11–01–93	Indef.
ST93–2529	Columbia Gas Transmission Corp.	Calvert Family Agency	02–03–93	G–S	2,530	N	F	02–01–93	Indef.
ST93–2530	Columbia Gas Transmission Corp.	C.E. Richner	02–03–93	G–S	2,274	N	F	02–01–93	Indef.
ST93–2531	Columbia Gulf Transmission Co.	Krupp & Associates	02–03–93	G–S	40,000	N	I	01–09–93	Indef.
ST93–2532	Columbia Gulf Transmission Co.	GGR Energy	02–03–93	G–S	100,000	N	I	01–22–93	Indef.
ST93–2533	Columbia Gulf Transmission Co.	Equitable Resources Marketing Co.	02–03–93	G–S	150,000	N	I	01–15–93	Indef.
ST93–2534	Columbia Gulf Transmission Co.	Citizens Gas Supply Corp	02–03–93	G–S	40,000	N	I	01–20–93	Indef.
ST93–2535	Arkla Energy Resources ..	Falling Tree Enterprises, Inc.	02–03–93	G–S	2,800	N	F	02–01–93	Indef.
ST93–2536	Arkla Energy Resources ..	NJR Energy Corp	02–03–93	G–S	500	N	F	02–01–93	Indef.
ST93–2537	Arkla Energy Resources ..	Pine Pipeline Co	02–03–93	B	2,000	A	F	02–01–93	Indef.
ST93–2538	Channel Industries Gas Co.	Tennessee Gas Pipeline co.	02–04–93	C	70,000	Y	I	01–06–93	Indef.
ST93–2539	Enercorp Pipeline Ltd	Texas Eastern Transmission Corp.	02–04–93	C	30,000	N	I	01–01–93	Indef.
ST93–2540	Williston Basin Inter. P/L Co.	Rainbow Gas Co	02–04–93	G–S	331,636	A	I	01–05–93	07–31–94
ST93–2541	Southern Natural Gas Co	Marshall County Gas District.	02–04–93	G–S	15,000	N	F	01–12–93	01–01–01
ST93–2542	Southern Natural Gas Co	Florida Gas Utility	02–04–93	G–S	100,000	N	I	01–23–93	Indef.
ST93–2543	Southern Natural Gas Co	National Gas & Oil Corp ..	02–04–93	G–S	2,592	N	F	01–01–93	10–31–93
ST93–2544	Southern Natural Gas Co	Centran Corp	02–04–93	G–S	100,000	N	I	01–02–93	Indef.
ST93–2545	Southern Natural Gas Co	Centran Corp	02–04–93	G–S	100,000	N	I	01–02–93	Indef.
ST93–2546	Phillips Gas Pipeline Co ..	Phillips Texas Border Pipeline Co.	02–04–93	B	45,000	Y	F	10–01–92	04–30–93
ST93–2547	Transcontinental Gas P/L Corp.	City of Butler	02–04–93	B	475	N	F	02–01–92	12–31–01
ST93–2548	Sabine Pipe Line Co	Texaco Exploration & Producing Inc.	02–05–93	G–S	50,000	N	I	02–01–93	Indef.
ST93–2549	K N Energy, Inc	Chevron USA, Inc	02–05–93	G–S	25,000	N	I	01–20–93	Indef.
ST93–2550	Kern River Gas Transmission Co.	U.S. Gas Transportation, Inc.	02–05–93	G–S	30,000	N	I	01–14–93	Indef.
ST93–2551	Channel Industries Gas Co.	Nat. Gas P/L Co. of America, et al.	02–05–93	C	30,000	N	I	01–07–93	Indef.
ST93–2552	Channel Industries Gas Co.	Corpus Christi Industrial P/L Co.	02–05–93	C	75,000	N	I	01–06–93	Indef.
ST93–2553	Valero Transmission, L.P .	Trunkline Gas Co	02–05–93	C	2,100	N	I	01–14–93	Indef.
ST93–2554	Tennessee Gas Pipeline Co.	Arco Natural Gas Marketing Inc.	02–05–93	G–S	500,000	N	I	12–01–92	Indef.

Docket No.*	Transporter/seller	Recipient	Date filed	Part 284 subpart	Est. Max. daily quantity**	AFF. Y/A/N***	Rate sch.	Date commenced	Projected termination date
ST93–2555	High Island Offshore System.	CNG Producing Co	02–05–93	K–S	20,000	N	I	01–01–93	Indef.
ST93–2556	United Gas Pipe Line Co .	MG Natural Gas Corp	02–05–93	B	24,000	N	I	01–23–93	Indef.
ST93–2557	United Gas Pipe Line Co .	Conoco Inc	02–05–93	G–S	20,000	N	I	01–29–93	05–29–93
ST93–2558	United Gas Pipe Line Co .	Enermax, Div. of Nukem, Inc.	02–05–93	G–S	104,800	N	I	01–29–93	05–29–93
ST93–2559	Columbia Gas Transmission Corp.	NGC Transportation, Inc ..	02–05–93	G–S	3,000	Y	F	01–01–93	Indef.
ST93–2560	Columbia Gas Transmission Corp.	Mason Producing, Inc	02–05–93	G–S	12,000	N	I	02–01–93	Indef.
ST93–2561	Columbia Gas Transmission.	Access Energy Corp	02–05–93	G–S	75	Y	F	02–01–93	Indef.
ST93–2562	Columbia Gas Transmission Corp.	Columbia Gas Development Corp.	02–05–93	G–S	800	A	F	02–01–93	Indef.
ST93–2563	Columbia Gas Transmission Corp.	Centran Corp	02–05–93	G–S	1,000	Y	I	02–01–93	Indef.
ST93–2564	Columbia Gas Transmission Corp.	Access Energy Corp	02–05–93	G–S	222	Y	F	02–01–93	Indef.
ST93–2565	Columbia Gas Transmission Corp.	Orange and Rockland Utilities, Inc.	02–05–93	B	33,000	Y	F	02–01–93	Indef.
ST93–2566	Columbia Gas Transmission Corp.	Baltimore Gas & Electric Co.	02–05–93	B	4,500	Y	F	02–01–93	Indef.
ST93–2568	Viking Gas Transmission Co.	Northern States Power Co	02–08–93	B	117,300	N	I	01–08–93	Indef.
ST93–2569	Western Gas Interstate Co.	NGC Transportation, Inc ..	02–08–93	G–S	60,000	N	I	12–10–92	Indef.
ST93–2570	Pacific Gas Transmission Co.	Pacific Gas & Electric Co	02–08–93	G–S	60,000	N	F	01–09–93	Indef.
ST93–2571	Pacific Gas Transmission Co.	Williams Gas Marketing Co.	02–08–93	G–S	25,000	N	I	02–19–93	Indef.
ST93–2572	Algonquin Gas Transmission Co.	Texas-Ohio Gas, Inc	02–08–93	G–S	120,000	N	I	01–08–92	Indef.
ST93–2573	Algonquin Gas Transmission Co.	Continental Energy Marketing, Inc.	02–08–93	G–S	50,000	N	I	01–19–93	Indef.
ST93–2574	Algonquin Gas Transmission Co.	Catamont Natural Gas, Inc.	02–08–93	G–S	75,000	N	I	02–01–92	Indef.
ST93–2575	Algonquin Gas Transmission Co.	American Central Gas	02–08–93	G–S	800,000	N	I	07–01–92	Indef.
ST93–2576	Algonquin Gas Transmission Co.	Continental Energy Marketing, Inc.	02–08–93	G–S	50,000	N	I	01–19–93	Indef.
ST93–2577	Algonquin Gas Transmission Co.	Tejas Hydrocarbons Co	02–08–93	G–S	1,000,000	N	I	06–02–92	Indef.
ST93–2578	Algonquin Gas Transmission Co.	Hadson Gas Systems, Inc	02–08–93	G–S	200,000	N	I	01–21–92	Indef.
ST93–2579	Algonquin Gas Transmission Co.	Distrigas of Massachusetts Corp.	02–8–93	G–S	10,200,000	N	I	01–28–93	Indef
ST93–2580	Algonquin Gas Transmission Co.	Yuma Gas Corp	02–08–93	G–S	71,000	N	I	04–26–92	Indef.
ST93–2581	Algonquin Gas Transmission Co.	New York Electric & Gas Corp.	02–08–93	G–S	16,830	N	I	01–02–92	Indef.
ST93–2582	Algonquin Gas Transmission Co.	Catamount Natural Gas, Inc.	02–8–93	G–S	100,000	N	I	11–01–92	Indef.
ST93–2583	Algonquin Gas Transmission Co.	Catamount Natural Gas, Inc.	02–08–93	G–S	75,000	N	I	04–14–92	Indef.

ST93–2584	Algonquin Gas Transmission Co.	Valley Gas Co	02–08–93	G–S	20,120	N	I	11–13–92	Indef.
ST93–2585	Algonquin Gas Transmission Co.	O&R Energy, Inc.	02–08–93	G–S	300,000	N	I	01–09–92	Indef.
ST93–2586	Algonquin Gas Transmission Co.	NGC Transportation , Inc .	02–08–93	G–S	625,000	N	I	12–10–92	Indef.
ST93–2587	Channel Industries Gas Co.	Texas Eastern Transmission Corp.	02–08–93	C	100,000	N	I	01–09–93	Indef.
ST93–2588	Channel Industries Gas Co.	Tennessee Gas Pipeline Co.	02—8–93	C	50,000	Y	I	01–07–93	Indef.
ST93–2589	National Fuel Gas Supply Corp.	Transfuel Marketing Co ...	02–08–93	G–S	50,000	N	I	01–08–93	05–08–93
ST93–2590	National Fuel Gas Supply Corp.	Direct Energy Marketing Limited.	02–08–93	G–S	4,087	N	I	01–27–93	05–27–93
ST93–2591	United Gas Pipe Line Co .	MG Natural Gas Corp	02–08–93	G–S	41,920	N	I	01–29–93	05–29–93
ST93–2592	Enogex Inc	Williams Natural Gas Co .	02–08–93	C	20,000	N	I	01–09–93	Indef.
ST93–2593	Enogex Inc	Northern Natural Gas	02–08–93	C	50,000	N	I	01–20–93	Indef.
ST93–2594	Colorado Interstate Gas Co.	Coastal Chem, Inc	02–09–93	G–S	5,080	A	F	01–21–93	04–30–93
ST93–2595	Columbia Gas Transmission Corp.	O&R Energy, Inc	02–09–93	G–S	1,215	N	I	02–01–93	Indef.
ST93–2596	Columbia Gas Transmission Corp.	Eastern Marketing Corp ...	02–09–93	G–S	50,000	Y	I	01–29–93	Indef.
ST93–2597	Columbia Gas Transmission Corp.	Krupp & Associates	02–09–93	G–S	1,620	N	F	02–01–93	Indef.
ST93–2599	Williams Natural Gas Co .	Premier Gas Co	02–09–93	G–S	1,000	N	I	01–15–93	Indef.
ST93–2600	Williams Natural Gas Co .	Global Petroleum Corp	02–09–93	G–S	3,000	N	I	01–16–93	Indef.
ST93–2601	Williams Natural Gas Co .	Kansas Municipal Gas Agency.	02–09–93	B	3,100	N	I	01–16–93	Indef.
ST93–2602	Tennessee Gas Pipeline Co.	Columbia Gas Development Corp.	02–10–93	G–S	521	N	I	02–01–93	Indef.
ST93–2604	Tennessee Gas Pipeline Co.	Citizen's Gas Supply Corp	02–10–93	G–S	30,000	N	I	02–01–93	Indef.
ST93–2605	Kern River Gas Transmission Co.	Tristar Gas Co	02–10–93	G–S	50,000	N	I	01–23–93	Indef.
ST93–2606	Northwest Pipeline Corp ..	LFC Gas Co	02–10–93	G–S	4,800	N	F	01–11–93	Indef.
ST93–2607	Transok Gas Transmission Co.	ANR Pipeline Co., et al	02–10–93	C	10,000	N	I	02–01–93	Indef.
ST93–2608	Transok Gas Transmission Co.	ANR Pipeline Co., et al	02–10–93	C	25,000	N	I	02–01–93	Indef.
ST93–2609	Transok Gas Transmission Co.	ANR Pipeline Co., et al	02–10–93	C	100,000	N	I	02–01–93	Indef.
ST93–2610	Channel Industries Gas Co.	Tennessee Gas Pipeline Co.	02–10–93	C	100,000	N	I	01–14–93	Indef.
ST93–2611	Channel Industries Gas Co.	Northern Natural Gas Co .	02–11–93	C	50,000	Y	I	01–12–93	Indef.
ST93–2612	Channel Industries Gas Co.	Energy Consultants, Inc ...	02–11–93	G–I	10,000	N	I	01–12–93	Indef.
ST93–2613	Channel Industries Gas Co.	Northern Natural Gas Co .	02–11–93	C	50,000	N	I	01–12–93	Indef.
ST93–2614	Kern River Gas Transmission Co.	Louis Dreyfus Energy Corp.	02–11–93	G–S	50,000	N	I	01–23–93	Indef.
ST93–2615	Gateway Pipeline Co	Vesta Energy Co	02–11–93	G–S	10,000	N	I	02–01–93	06–01–93
ST93–2616	United Gas Pipe Line Co .	Philbro Energy USA Inc ...	02–11–93	G–S	314,400	N	I	02–03–93	06–03–93
ST93–2617	United Gas Pipe Line Co .	Tenngasco Corp	02–11–93	G–S	440,160	N	I	02–03–93	06–03–93
ST93–2618	United Gas Pipe Line Co .	MG Natural Gas Corp	02–11–93	G–S	41,920	N	I	02–03–93	06–03–93
ST93–2619	United Gas Pipe Line Co .	Enermax, Division of Nukem, Inc.	02–11–93	G–S	104,800	N	I	02–03–93	06–03–93

Docket No.*	Transporter/seller	Recipient	Date filed	Part 284 subpart	Est. Max. daily quantity**	AFF. Y/A/N***	Rate sch.	Date commenced	Projected termination date
ST93–2620	United Gas Pipe Line Co .	KCS Energy Marketing, Inc.	02–11–93	G–S	78,600	N	I	02–03–93	06–03–93
ST93–2621	Northwest Pipeline Corp ..	Grand Valley Gas Co	02–11–93	G–S	7,250	N	I	02–01–93	Indef.
ST93–2622	Natural Gas P/L Co. of America.	EP Operating Co	02–11–93	G–S	25,000	N	I	12–14–92	Indef.
ST93–2623	Natural Gas P/l Co. of America.	American Central Gas Cos., Inc.	02–11–93	G–S	30,000	N	I	01–27–93	Indef.
ST93–2624	Natural Gas P/L Co. of America.	Parker & Parsley Development Co.	02–11–93	G–S	10,000	N	I	02–01–93	Indef.
ST93–2625	ONG Transmission Co	Natural Gas P/L Co. of America.	02–12–93	C	20,000	N	I	01–27–93	Indef.
ST93–2626	Texas Eastern Corp	Yuma Gas Corp	02–12–93	G–S	10,000	N	I	01–21–93	Indef.
ST93–2627	Williston Basin Inter. P/L Co.	Koch Hydorcarbon Co	02–12–93	G–S	271,325	A	I	01–15–93	05–01–93
ST93–2628	Williston Basin Inter. P/L Co.	Western Gas Resources, Inc.	02–12–93	G–S	266,235	A	I	01–29–93	08–31–93
ST93–2629	Natural Gas P/L Co. of America.	Engroup, Inc	02–12–93	G–S	5,000	N	I	02–01–93	Indef.
ST93–2630	Natural Gas P/L Co. of America.	Coastal Gas Marketing Co	02–12–93	G–S	100,000	N	I	01–13–93	Indef.
ST93–2631	Columbia Gas Transmission Corp.	Mead Corp	02–12–93	G–S	2,250	Y	F	02–01–93	Indef.
ST93–2632	Columbia Gas Transmission Corp.	D.C. Malcolm, Inc	02–12–93	G–S	500	N	I	02–01–93	Indef.
ST93–2633	Columbia Gas Transmission Corp.	Consumers Gas Utility Co., et al.	02–12–93	B	800	N	I	02–06–93	Indef.
ST93–2634	Columbia Gas Transmission Corp.	Huntington Oklahoma Oil Co.	02–12–93	G–S	1,790	N	F	02–01–93	0Indef
ST93–2635	Colorado Interstate Gas Co.	Coastal Oil & Gas Corp	02–12–93	G–S	40,000	Y	F	01–26–93	01–26–03
ST93–2636	Wyoming Interstate Co., Ltd.	Questar Pipeline Co., Ltd	02–12–93	G–S	80,000	N	I	11–25–93	Indef.
ST93–2637	ANR Pipeline Co	Coenergy Ventures, Inc	02–12–93	G–S	100,000	N	I	02–01–93	Indef.
ST93–2638	ANR Pipeline Co	CMS Gas Marketing	02–12–93	G–S	150,000	N	F	02–01–93	Indef.
ST93–2639	ANR Pipeline Co	Texas-Ohio Gas, Inc	02–12–93	G–S	30,000	N	I	02–01–93	Indef.
ST93–2640	ANR Pipeline Co	Dayton Power and Light Co.	02–12–93	B	100,000	N	I	02–01–93	Indef.
ST93–2641	ANR Pipeline Co	Nerco Oil & Gas, Inc	02–12–93	G–S	50,000	N	I	02–01–93	Indef.
ST93–2642	ANR Pipeline Co	EMC Gas Transmission Co.	02–12–93	G–S	30,000	N	F	02–01–93	Indef.
ST93–2643	ANR Pipeline Co	Chevron U.S.A	02–12–93	G–S	50,000	N	I	01–27–93	Indef.
ST93–2644	Superior Offshore Pipeline Co.	Citizens Gas	02–16–93	B	18,250,000	N	I	12–14–92	Indef.
ST93–2645	Viking Gas Transmission Co.	Midwest Gas	02–16–93	B	950	N	F	02–05–93	Indef.
ST93–2646	Texas Gas Gathering	Natural Gas P/L Co. of America.	02–16–93	C	600	N	I	01–01–93	Indef.
ST93–2647	Texas Gas Gathering	Natural Gas P/L Co. of America.	02–16–93	C	15,725	N	I	01–01–93	Indef.
ST93–2648	Texas Gas Gathering	Natural Gas P/L Co. of Amer., et al.	02–16–93	C	22,522	N	I	01–01–93	Indef.
ST93–2649	Texas Gas Gathering	Natural Gas P/L Co. of Amer., et al.	02–16–93	C	2,000	N	I	10–01–92	Indef.

ST93–2650	Algonquin Gas Transmission Co.	Texas Eastern Transmission Corp.	02–16–93	G	200,000	N	I	02–03–93	Indef.
ST93–2651	Algonquin Gas Transmission Co.	Providence Gas Co	02–16–93	G	800	N	F	02–03–93	Indef.
ST93–2652	Algonquin Gas Transmission Co.	Texas Eastern Transmission Corp.	02–16–93	G	420,000	N	I	02–01–93	Indef.
ST93–2653	Algonquin Gas Transmission Co.	Texas Eastern Transmission Corp.	02–16–93	G	420,000	N	I	02–02–93	Indef.
ST93–2654	Algonquin Gas Transmission Co.	Tennessee Gas Pipeline Co.	02–16–93	G	4,400,000	N	I	01–30–93	Indef.
ST93–2655	Algonquin Gas Transmission Co.	Tennessee Gas Pipeline Co.	02–16–93	G	4,400,000	N	I	01–30–93	Indef.
ST93–2656	Algonquin Gas Transmission Co.	Texas Eastern Transmission Corp.	02–16–93	G	900,000	N	I	02–01–93	Indef.
ST93–2657	Algonquin Gas Transmission Co.	Iroquois Gas Transmission System.	02–16–93	G	900,000	N	I	02–01–93	Indef.
ST93–2658	Algonquin Gas Transmission Co.	Texas Eastern Transmission Corp.	02–16–93	G	50,000	N	I	02–01–93	Indef.
ST93–2659	Algonquin Gas Transmission Co.	Texas Eastern Transmission Corp.	02–16–93	G	50,000	N	I	02–01–93	Indef.
ST93–2660	ANR Pipeline Co	Howard Energy Co., Inc	02–16–93	G–S	100,000	N	I	02–01–93	Indef.
ST93–2661	ANR Pipeline Co	BP Gas Inc	02–16–93	G–S	100,000	N	F	02–01–93	Indef.
ST93–2662	ANR Pipeline Co	BP Gas Inc	02–16–93	G–S	100,000	N	F	02–01–93	Indef.
ST93–2663	Panhandle Eastern Pipe Line Co.	Unigas Energy, Inc	02–16–93	G–S	11,682	N	F	02–01–93	Indef.
ST93–2664	Panhandle Eastern Pipe Line Co.	Yuma Gas Corp	02–16–93	G–S	600	N	F	01–16–93	Indef.
ST93–2665	Trunkline Gas Co	Dowling Energy, Inc	02–16–93	G–S	5,000	N	I	01–30–93	Indef.
ST93–2666	Florida Gas Transmission Co.	Feldspar Corp	02–16–93	G–S	323	N	I	01–18–93	Indef.
ST93–2667	Arkla Energy Resources	Red River Gas Pipeline Corp.	02–16–93	B	50,000	N	I	02–09–93	Indef.
ST93–2668	Sea Robin Pipeline Co	Tennessee Gas Pipeline Co.	02–16–93	G–S	4,800	N	I	01–01–93	03–31–93
ST93–2669	Texas Eastern Transmission Corp.	United Cities Gas Co	02–17–93	B	10,000	N	I	02–06–93	Indef.
ST93–2670	Texas Eastern Transmission Corp.	City of Kennett	02–17–93	B	50,000	N	I	02–01–93	Indef.
ST93–2671	Texas Eastern Transmission Corp.	Penn Fuel Gas, Inc	02–17–93	B	30,000	N	I	02–01–93	Indef.
ST93–2672	Texas Eastern Transmission Corp.	Global Petroleum Corp	02–17–93	G–S	75,000	N	I	02–03–93	Indef.
ST93–2673	Texas Eastern Transmission Corp.	CMS Gas Marketing Co	02–17–93	G–S	2,200	N	I	01–25–93	Indef.
ST93–2674	Mississippi River Trans. Corp.	North Canadian Marketing Corp.	02–17–93	G–S	20,000	N	I	02–01–93	Indef.
ST93–2675	Mississippi River Trans. Corp.	Jefferson Smurfit Corp	02–17–93	G–S	7,800	N	F	02–01–93	Indef.
ST93–2676	Transcontinental Gas P/L Corp.	Gaslantic Corp	02–17–93	G–S	20,000	N	I	01–22–93	Indef.
ST93–2677	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–17–93	G–S	500,000	A	I	10–01–90	Indef.
ST93–2678	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–17–93	G–S	500,000	A	I	10–01–90	Indef.
ST93–2679	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–17–93	G–S	500,000	A	I	10–01–90	Indef.
ST93–2680	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–17–93	G–S	500,000	A	I	10–01–90	Indef.

Docket No.*	Transporter/seller	Recipient	Date filed	Part 284 subpart	Est. Max. daily quantity**	AFF. Y/A/N***	Rate sch.	Date commenced	Projected termination date
ST93–2681	Northern Natural Gas Co .	Great Falls Gas Co	02–18–93	G–S	15,000	N	F/I	02–01–93	Indef.
ST93–2682	ONG Transmission Co	Arkla Energy Resources	02–18–93	C	20,000	N	I	02–01–93	Indef.
ST93–2683	Tennessee Gas Pipeline Co.	NGC Transportation, Inc	02–18–93	G–S	10,500	N	F	02–01–93	Indef.
ST93–2684	Tennessee Gas Pipeline Co.	Altresco Pittsfield, L.P	02–18–93	G–S	2,000	N	F	02–06–93	Indef.
ST93–2685	Northwest Pipeline Corp	Williams Field Services	02–18–93	G–S	2,000	N	I	01–01–93	Indef.
ST93–2686	Northwest Pipeline Corp	Williams Gas Processing Co.	02–18–93	G–S	2,000	N	I	01–01–93	Indef.
ST93–2687	Northwest Pipeline Corp	Mitchell & Mitchell Energy Group.	02–18–93	G–S	1,000	N	I	02–11–93	Indef.
ST93–2688	Columbia Gulf Transmission Co.	Yuma Gas Corp	02–18–93	G–S	70,000	N	I	02–01–93	Indef.
ST93–2689	Columbia Gulf Transmission Co.	Polaris Pipeline Corp	02–18–93	G–S	100,000	N	I	01–28–93	Indef.
ST93–2690	Columbia Gulf Transmission Co.	Oryx Gas Marketing L.P	02–18–93	G–S	70,000	N	I	01–28–93	Indef.
ST93–2691	Columbia Gulf Transmission Co.	Entrade Corp	02–18–93	G–S	50,000	N	I	01–29–93	Indef.
ST93–2692	Columbia Gulf Transmission Co.	Conoco Inc	02–18–93	G–S	75,000	N	I	01–29–93	Indef.
ST93–2693	Columbia Gulf Transmission Co.	Brooklyn Interstate Nat. Gas Corp.	02–18–93	G–S	50,000	N	I	02–01–93	Indef.
ST93–2694	Williston Basin Inter. P/L Co.	Cenex	02–19–93	G–S	6,318	A	I	01–20–93	12–31–93
ST93–2695	Tennessee Gas Pipeline Co.	Mississippi Valley Gas Co	02–19–93	B	20,000	N	I	01–20–93	Indef.
ST93–2696	Tennessee Gas Pipeline Co.	Continental Energy Marketing, Inc.	02–19–93	G–S	50,000	N	I	01–20–93	Indef.
ST93–2697	Tennessee Gas Pipeline Co.	Cornerstone Production Corp.	02–19–93	G–S	150,000	N	I	01–20–93	Indef.
ST93–2698	United Gas Pipe Line Co .	American Central Cos., Inc.	02–19–93	G–S	157,200	N	I	02–11–93	06–11–93
ST93–2699	United Gas Pipe Line Co .	Prior Intrastate Corp	02–19–93	G–S	524,000	N	I	02–11–93	06–11–93
ST93–2700	United Gas Pipe Line Co .	Monsanto Co	02–19–93	G–S	100,000	N	I	02–01–93	06–01–93
ST93–2701	United Gas Pipe Line Co .	Polaris Pipeline Corp	02–19–93	G–S	20,960	N	I	02–03–93	06–03–93
ST93–2702	United Gas Pipe Line Co .	Texaco Gas Marketing Inc	02–19–93	G–S	209,600	N	I	02–11–93	06–11–93
ST93–2703	Arkla Energy Resources	Delhi Gas Pipeline Co	02–19–93	B	150,000	N	I	02–18–93	Indef.
ST93–2704	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2705	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2706	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2707	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2708	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2709	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2710	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2711	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.

ST93–2712	Natural Gas P/L Co. of America.	Midcon Gas Services Corp.	02–19–93	G–S	200,000	A	I	10–01–90	Indef.
ST93–2713	Natural Gas P/L Co. of America.	Panhandle Trading Co	02–19–93	G–S	150,000	N	I	02–06–93	Indef.
ST93–2714	Trailblazer Pipeline Co	Natural Gas P/L Co. of America.	02–19–93	G	353,000	A	I	12–11–92	Indef.
ST93–2715	Channel Industries Gas Co.	Tennessee Gas Pipeline Co.	02–22–93	C	75,000	N	I	01–23–93	Indef.
ST93–2716	Midwestern Gas Transmission Co.	Western Gas Marketing, Inc.	02–22–93	G–S	100,000	N	I	02–01–93	Indef.
ST93–2717	Kern River Gas Transmission Co.	Texaco Gas Marketing, Inc..	02–22–93	G–S	35,000	N	I	01–23–93	Indef.
ST93–2718	Tennessee Gas Pipeline Co.	Columbia Gas of Kentucky, Inc.	02–22–93	G–S	1,000	N	F	02–01–93	Indef.
ST93–2719	Tennessee Gas Pipeline Co.	Enron Gas Marketing, Inc	02–22–93	G–S	703,297	N	I	02–01–93	Indef.
ST93–2720	Tennessee Gas Pipeline Co.	Appalachian Gas Sales	02–22–93	G–S	15,000	N	I	02–01–93	Indef.
ST93–2721	Tennessee Gas Pipeline Co.	Stellar Gas Co	02–22–93	G–S	10,000	N	I	01–25–93	Indef.
ST93–2722	Questar Pipeline Co	Colorado Interstate Gas Co., et al.	02–22–93	G	10,000	N	I	02–01–93	Indef.
ST93–2723	ANR Pipeline Co	Altresco Lynn, Inc	02–23–93	G–S	41,500	N	F	01–01–92	Indef.
ST93–2724	ANR Pipeline Co	Indeck-Corinth L.P	02–23–93	G–S	11,000	N	F	10–01–92	Indef.
ST93–2725	ANR Pipeline Co	Sithe/Independence Power Partners.	02–23–93	G–S	120,000	Y	F	04–01–92	Indef.
ST93–2726	ANR Pipeline Co	Michigan Gas Utilities	02–23–93	B	50,000	Y	I	02–04–93	Indef.
ST93–2727	ANR Pipeline Co	Kerr-McGee Corp	02–23–93	G–S	100,000	N	I	02–05–93	Indef.
ST93–2728	ANR Pipeline Co	Equitable Resources Marketing Co.	02–23–93	G–S	100,000	Y	I	02–05–93	Indef.
ST93–2729	Colorado Interstate Gas Co.	Phillips Pipe Line Co	02–23–93	G–S	200	N	F	07–01–92	06–30–93
ST93–2730	ANR Pipeline Co	O & R Energy, Inc	02–23–93	G–S	50,000	N	I	02–12–93	Indef.
ST93–2731	ANR Pipeline Co	Consumers Power Co	02–23–93	B	1,100	N	F	03–01–92	01–31–97
ST93–2732	Great Lakes Gas Trans., L.P.	Poco Petroleums Ltd	02–23–93	G–S	30,000	N	I	12–01–92	Indef.
ST93–2733	Great Lake Gas Trans., L.P.	Coastal Gas Marketing Co	02–23–93	G–S	200,000	A	I	12–24–92	Indef.
ST93–2734	Tennessee Gas Pipeline Co.	North American Resources Co.	02–23–93	G–S	16,000	N	F	02–01–93	11–01–93
ST93–2735	United Gas Pipe Line Co .	Midcon Marketing Corp	02–23–93	G–S	74,198	N	F	02–15–93	06–15–93
ST93–2736	United Gas Pipe Line Co .	Arkla Energy Marketing Co.	02–23–93	G–S	6,850	N	I	02–16–93	06–16–93
ST93–2737	United Gas Pipe Line Co .	Enermax	02–23–93	G–S	104,800	N	I	02–12–93	06–12–93
ST93–2738	United Gas Pipe Line Co .	Excel Gas Marketing, Inc .	02–23–93	G–S	102,704	N	I	02–16–93	06–16–93
ST93–2739	United Gas Pipe Line Co .	Amax Oil & Gas, Inc	02–23–93	G–S	20,960	N	I	02–16–93	06–16–93
ST93–2740	United Gas Pipe Line Co .	Mid Louisiana Marketing Co.	02–23–93	G–S	30,000	N	F	02–02–93	06–02–93
ST93–2741	United Gas Pipe Line Co .	Yuma Gas Corp	02–23–93	G–S	78,600	N	I	02–16–93	06–16–93
ST93–2742	United Gas Pipe Line Co .	American Central Gas Cos., Inc.	02–23–93	G–S	157,200	N	I	02–16–93	06–16–93
ST93–2743	Columbia Gas Transmission Corp.	Clinton Gas Marketing, Inc.	02–22–93	G–S	4,984	N	F	02–01–93	Indef.
ST93–2744	Columbia Gas Transmission Corp.	Penn Fuel Gas, Inc	02–22–93	B	40,000	Y	I	02–01–93	Indef.
ST93–2745	Valero Transmission, L.P .	United Gas Pipeline Co	02–22–93	C	7,000	N	I	02–01–93	Indef.
ST93–2746	Louisiana Resources Pipeline Co.	Pontchartrain Natural Gas	02–22–93	C	50,000	N	I	02–06–93	Indef.

Docket No *	Transporter/seller	Recipient	Date filed	Part 284 subpart	Est. Max. daily quantity**	AFF. Y/A/N***	Rate sch.	Date commenced	Projected termination date
ST93–2747	Transok Gas Transmission Co.	ANR Pipeline Co., et al	02–23–93	C	1,000	N	I	02–08–93	Indef.
ST93–2748	Transok Gas Transmission Co.	ANR Pipeline Co., et al	02–23–93	C	20,000	N	I	01–01–92	Indef.
ST93–2749	Transok Gas Transmission Co.	ANR Pipeline Co., et al	02–23–93	G–S	20,000	N	I	01–01–92	Indef.
ST93–2750	Texas Gas Transmission Corp.	Equitable Resources Marketing Co.	02–23–93	G–S	20,000	N	I	02–02–93	Indef.
ST93–2751	Texas Gas Transmission Corp.	NGC Transportation, Inc.	02–23–93	G–S	20,000	N	I	02–05–93	Indef.
ST93–2752	Transok, Gas Transmission Co.	ANR Pipeline Co., et al	02–24–93	C	20,000	N	I	02–01–92	Indef.
ST93–2753	Kern River Gas Transmission Co.	Union Pacific Fuels, Inc	02–24–93	G–S	100,000	N	F	02–01–93	Indef.
ST93–2754	Natural Gas P/L Co. of America.	Access Energy Corp	02–24–93	G–S	50,000	N	I	08–01–90	Indef.
ST93–2755	Natural Gas P/L Co. of America.	Access Energy Corp	02–24–93	G–S	40,000	N	I	08–01–90	Indef.
ST93–2756	Iroquois Gas Trans. System, L.P.	Southern Connecticut Gas Co.	02–24–93	B	380,586	N	I	02–29–92	Indef.
ST93–2757	Columbia Gas Transmission Corp.	Vineyard Oil & Gas Co	02–24–93	G–S	1,000	Y	I	02–16–93	Indef.
ST93–2758	Columbia Gas Transmission Corp.	Paramount Transmission Corp.	02–24–93	G–S	10,000	N	F	02–01–93	Indef.
ST93–2759	Columbia Gas Transmission Corp.	Bradco Oil Co	02–24–93	G–S	716	N	F	02–01–93	Indef.
ST93–2760	Columbia Gas Transmission Corp.	Paramount Transmission Corp.	02–24–93	B	5,000	N	I	02–12–93	Indef.
ST93–2761	Oasis Pipe Line Co	Natural Gas P/L Co. of America.	02–24–93	C	100,000	N	I	02–01–93	Indef.
ST93–2762	Houston Pipe Line Co	Texas Eastern Transmission Corp.	02–24–93	C	20,000	N	I	02–01–93	Indef.
ST93–2763	Houston Pipe Line Co	Transcontinental Gas P/L Corp.	02–24–93	C	100,000	N	I	01–27–93	Indef.
ST93–2764	Houston Pipe Line Co	Tennessee Gas Pipeline Co.	02–24–93	C	20,000	N	I	02–04–93	Indef.
ST93–2765	Houston Pipe Line Co	Florida Gas Transmission Co.	02–24–93	C	20,000	N	I	02–01–93	Indef.
ST93–2766	Enogex Inc	Williams Natural Gas Co	02–24–93	C	50,000	N	I	02–02–93	Indef.
ST93–2767	Panhandle Eastern Pipe Line Co.	Amgas, Inc	02–24–93	G–S	20	N	I	02–01–93	Indef.
ST93–2768	Panhandle Eastern Pipe Line Co.	Aquila Energy Marketing Corp.	02–24–93	G–S	1,500	N	F	02–01–93	Indef.
ST93–2769	Panhandle Eastern Pipe Line Co.	OXY USA Inc	02–24–93	G–S	50,000	N	F	02–01–93	Indef.
ST93–2770	Panhandle Eastern Pipe Line Co.	Amgas, Inc	02–24–93	G–S	20	N	F	02–01–93	Indef.
ST93–2771	Panhandle Eastern Pipe Line Co.	MG Natural Gas Corp	02–24–93	G–S	3,000	N	F	02–01–93	Indef.
ST93–2772	Panhandle Eastern Pipe Line Co.	Oxy USA	02–24–93	G–S	150,000	N	I	02–01–93	Indef.
ST93–2773	Panhandle Eastern Pipe Line Co.	Western Gas Marketing Inc.	02–24–93	G–S	50,000	N	F	02–01–93	Indef.

ST93–2774	Williston Basin Inter. P/L Co.	Amoco Energy Trading Corp.	02–25–93	G–S	18,200	A	I	01–26–93	01–25–95
ST93–2775	Trunkline Gas Co	Enron Gas Marketing, Inc	02–25–93	G–S	50,000	N	I	02–04–93	Indef.
ST93–2776	Trunkline Gas Co	Coastal Gas Marketing Co	02–25–93	G–S	100,000	N	I	02–01–93	Indef.
ST93–2777	Trunkline Gas Co	Catex Energy, Inc	02–25–93	G–S	75,000	N	I	02–01–93	Indef.
ST93–2778	Trunkline Gas Co	Triumph Natural Gas. Inc	02–25–93	G–S	19,512	N	I	02–01–93	Indef.
ST93–2779	Trunkline Gas Co	Vesta Energy Co	02–25–93	G–S	10,000	N	I	02–01–93	Indef.
ST93–2780	Trunkline Gas Co	Enron Gas Marketing, Inc	02–25–93	G–S	100,000	N	I	02–01–93	Indef.
ST93–2781	CNG Transmission Corp	NYSEG Systems Supply	02–25–93	G–S	100,000	N	I	02–01–93	Indef.
ST93–2782	CNG Transmission Corp	Owens Illinois, Inc	02–25–93	G–S	20,000	N	I	02–01–93	Indef.
ST93–2783	CNG Transmission Corp	Potomac Elect. Power System Supply.	02–25–93	G–S	20,000	A	I	02–06–93	Indef.
ST93–2784	Valero Transmission, L.P	El Paso Natural Gas Co	02–25–93	C	6,200	N	I	02–01–93	Indef.
ST93–2785	Northern Natural Gas Co	Panda Resources, Inc	02–25–93	G–S	500,000	N	I	02–01–93	Indef.
ST93–2786	Northern Natural Gas Co	Eastex Hydrocarbons, Inc	02–25–93	G–S	50,000	N	F/I	01–21–93	Indef.
ST93–2787	Arkla Energy Resources	ARCO Natural Gas Marketing, Inc.	02–25–93	G–S	10,204	N	F	01–01–93	Indef.
ST93–2788	Williams Natural Gas Co	Texarkoma Transportation Co.	02–25–93	G–S	10,000	N	I	02–01–93	Indef.
ST93–2789	Natural Gas P/L Co. of America.	Northern Illinois Gas Co	02–26–93	G–S	16,000	N	F	02–01–93	12–01–95
ST93–2790	Natural Gas P/L Co. of America.	A.E. Stanley Manufacturing Co.	02–26–93	G–S	8,000	N	I	02–10–92	Indef.
ST93–2791	Lone Star Gas Co	Arkla Energy Resources	02–26–93	C	15,000	N	I	04–01–92	Indef.
ST93–2792	Lone Star Gas Co	El Paso Natural Gas Co. et al.	02–26–93	C	100,000	N	I	03–23–92	Indef.
ST93–2793	Gulf Energy Pipeline Co	Trunkline Gas Co	02–26–93	C	10,000	N	I	04–01–92	Indef.
ST93–2794	Colorado Interstate Gas Co.	CNG Producing Co	02–25–93	G–S	4,000	N	F	02–01–93	01–31–03
ST93–2795	Columbia Gas Transmission Corp.	Alliance Resources Corp	02–25–93	G–S	144	N	F	02–01–93	Indef.
ST93–2796	Columbia Gas Transmission Corp.	Baiden Gas Co	02–25–93	G–S	618	N	F	02–01–93	Indef.
ST93–2797	Delhi Gas Pipeline Corp	Nat. Gas P/L Co. of America, et al.	02–26–93	C	3,500	N	I	02–06–93	Indef.
ST93–2798	Delhi Gas Pipeline Corp	Arkla Energy Resources, et al.	02–26–93	C	5,000	N	I	02–06–93	Indef.
ST93–2799	Delhi Gas Pipeline Corp	ANR Pipeline Co., et al	02–26–93	C	25,000	N	I	02–01–93	Indef.
ST93–2800	Valero Intermission, L.P	Transcontinental Gas Co	02–26–93	C	2,000	N	I	02–05–93	Indef.
ST93–2801	Ozark Gas Transmission System.	Arkansas-Oklahoma Gas Co.	02–26–93	B	100,000	N	F/I	02–01–93	Indef.
ST93–2802	Panhandle Eastern Pipeline Co.	Western Gas Resources, Inc.	02–26–93	G–S	100,000	N	I	01–30–93	Indef.

*Notice of Transactions Does not Constitute a Determination That Filings Comply With Commission Regulations in Accordance With Order No. 436 (Final Rule and Notice Requesting Supplemental Comments, 50 FR 42,372, 10/10/85).

**Estimated Maximum Daily Volumes Includes Volumes Reported by the Filing Company in MMBTU, MCF and DT.

***Affiliation of Reporting Company to Entities Involved in the Transaction. A "Y" Indicates Affiliation, An "A" Indicates Marketing Affiliation, and a "N" Indicates No Affiliation.

[FR Doc. 93–8787 Filed 4–15–93; 8:45 am]
BILLING CODE 6717–01–M

[Docket No. JD93–06881T North Dakota–4]

North Dakota; NGPA Notice of Determination by Jurisdictional Agency Designating Tight Formation

April 12, 1993.

Take notice that on April 7, 1993, the Oil and Gas Division of the North Dakota Industrial Commission (North Dakota), submitted the above-referenced notice of determination pursuant to § 271.703(c)(3) of the Commission's regulations, that the Winnipeg Formation, underlying certain lands in Williams County, North Dakota, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978. The area of application consists of Section 22, Township 156 North, Range 96 West.

The notice of determination also contains North Dakota's findings that the referenced portion of the Winnipeg Formation meets the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capital Street, NE., Washington DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8920 Filed 4–15–93; 8:45 am]
BILLING CODE 6717–01–M

[Project No. 11100–002, Idaho]

Hammond Hydroelectric Company; Surrender of Preliminary Permit

April 12, 1993.

Take notice that Hammond Hydroelectric Company, Permittee for the Hammond Project No. 11100, has requested that its preliminary permit be terminated. The preliminary permit for Project No. 11100 was issued June 25, 1991, and would have expired May 31, 1994. The project would have been located on Challis and Bear Creeks within the Challis National Forest in Custer County, Idaho.

The Permittee filed the request on February 22, 1993, and the preliminary permit for Project No. 11100 shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR part 4, may be filed on the next business day.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8918 Filed 4–15–93; 8:45 am]
BILLING CODE 6717–01–M

[Project No. 10880–001, Idaho]

Contractor's Power Group, Inc.; Surrender of Preliminary Permit

April 12, 1993.

Take notice that Contractor's Power Group, Inc., Permittee for the Ryegrass Project No. 10880, has requested that its preliminary permit be terminated. The preliminary permit for Project No. 10880 was issued June 28, 1990, and would have expired May 31, 1993. The project would have been located on the Richfield Canal and Big Wood River, in Lincoln and Blaine Counties, Idaho.

The Permittee filed the request on April 7, 1993, and the preliminary permit for Project No. 10880 shall remain in effect through the thirtieth day after issuance of this notice unless that day is a Saturday, Sunday or holiday as described in 18 CFR 385.2007, in which case the permit shall remain in effect through the first business day following that day. New applications involving this project site, to the extent provided for under 18 CFR part 4, may be filed on the next business day.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8919 Filed 4–15–93; 8:45 am]
BILLING CODE 6717–01–M

[Docket No. RP92–237–000]

Alabama-Tennessee Natural Gas Company; Informal Settlement Conference

April 12, 1993.

Take notice that an informal settlement conference will be convened in this proceeding on April 16, 1993, at 9 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street, NE., Washington, DC, for the purpose of exploring the possible settlement of the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant, as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, please contact Irene E. Szopo at (202) 208–1602, or David R. Cain at (202) 208–0917.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8913 Filed 4–15–93; 8:45 am]
BILLING CODE 6717–01–M

[Docket No. RP93–102–000]

Columbia Gas Transmission Corporation Proposed Changes in FERC Gas Tariff

April 12, 1993.

Take notice that Columbia Gas Transmission Corporation (Columbia) on April 8, 1993, tendered for filing the following proposed changes to its FERC Gas Tariff, First Revised Volume No. 1, to be effective May 1, 1993:

Primary Tariff Sheets

Fifth Revised Sheet No. 30B05
Original Sheet No. 30B06
Second Revised Sheet No. 126
First Revised Sheet No. 177
Original Sheet No. 178

Alternate Tariff Sheets

Alternate Fifth Revised Sheet No. 30B05
Alternate Original Sheet No. 30B06
Second Revised Sheet No. 126
Alternate First Revised Sheet No. 177
Original Sheet No. 178

Columbia states that the foregoing primary and alternate tariff sheets set forth the procedures and proposed allocation factors for recovery of the rebilled Order 94/473 cost. By this filing Columbia is seeking recovery of rebilled amounts payable to panhandle Eastern Pipe Line Corporation (Panhandle) pursuant to a settlement approved by the Commission's order dated February 11, 1993, in Docket Nos. RP85–203–011, *et al.* Columbia proposes to recover the amounts over a twelve-month period. The primary tariff sheets set forth the fixed monthly demand surcharge based on the as-billed methodology, *i.e.*, for Panhandle the allocation will be based upon firm sales and transportation entitlements for the period June 1, 1988 through May 31, 1989. The alternate tariff sheets set forth the fixed monthly demand surcharge based on firm sales and converted firm transportation at February 11, 1993, the date of the Commission's order.

Columbia states that copies of the filing are being mailed by Columbia to all jurisdictional customers and state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, Union Center Plaza Building, 825 North Capitol Street, NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before April 19, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of Columbia's filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8915 Filed 4–15–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–100–000]

Dakota Gasification Company (Successor-in-Interest to Great Plains Gasification Associates, et al.); Motion Requesting Initiation of Proceeding

April 12, 1993.

Take notice that on April 5, 1993, the Wisconsin Distributor Group (WDG), Michigan Consolidated Gas Company (MichCon) and Michigan Gas Utilities (MGU) (collectively WDG *et al.*) filed a motion requesting initiation of a proceeding under Opinion No. 119 and issuance of a cease and desist order. The WDG *et al.* state that this motion is being filed pursuant to the express provision in Opinion No. 119 that any party has the opportunity to challenge the calculation of the rate under the pricing formula approved by the Commission in Opinion No. 119 for the cost of synthetic coal gas sold by Dakota Gasification Company (Dakota), successor-in-interest to Great Plains Gasification Associates, to the pipelines purchasing the Dakota gas.

By its Motion, the WDG *et al.* request that the Commission immediately initiate a proceeding to determine that (1) the price of synthetic coal gas that Dakota charges ANR Pipeline Company (ANR) is contrary to the intent, spirit and express terms of Opinion No. 119 as the price is in the order of two times the prevailing market price for natural gas, and (2) the price permitted to be charged by ANR to its customers can be no more than the prevailing market price of domestic natural gas at the wellhead, consistent with the ratepayer protections embodied in Opinion No. 119. The WDG *et al.* further request that the Commission order (1) Dakota immediately to cease and desist charging to ANR prices for synthetic coal gas higher than the prevailing market prices that ANR's customers otherwise pay for natural gas in the field, and (2) ANR immediately to cease and desist billing to its customers any costs of Dakota synthetic coal gas above the cost that ANR's ratepayers otherwise pay to purchase natural gas in the field.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with 18 CFR 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before May 3, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8910 Filed 4–15–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. RP93–101–000]

National Fuel Gas Supply Corporation; Petition To Waive Tariff Provision

April 12, 1993.

Take notice that on April 7, 1993 National Fuel Gas Supply Corporation ("National") filed a Petition For Waiver of Certain Part 284 Reporting Requirements. National states that its Petition for Waiver seeks the same waivers of reporting requirements granted by the Commission in *Tennessee Gas Pipeline Company*, 62 FERC ¶ 61,250 (3/16/93). Specifically, National requests a waiver of:

18 CFR 284.106 (a), (b), (c), (d) and (g), 18 CFR 284.222 and 18 CFR 284.223 (d), (e) and (f) to the extent necessary to allow National to implement non-permanent capacity release transactions on National's system without the necessity of filing initial reports, subsequent reports, annual reports, notifications of termination, and storage reports reflecting such capacity release transactions; and

18 CFR 284.106(a)(3)(iv), to the extent necessary to allow National to add or delete receipt and delivery points without the necessity to file subsequent reports under 18 CFR 284.106(b).

National proposes an effective date of May 1, 1993 for this waiver, to coincide with National's requested effective date for its March 18, 1993 Order No. 636 compliance filing in Docket No. RS92–21–000.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20428, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214. All such motions or protests should be filed on or before April 19, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8914 Filed 4–15–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–288–000]

Natural Gas Pipeline Company of America; Request Under Blanket Authorization

April 12, 1993.

Take notice that on April 7, 1993, Natural Gas Pipeline Company of America (Natural) 701 East 22nd Street, Lombard, Illinois 60148, filed in Docket No. CP93–288–000 a request pursuant to sections 157.205 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to abandon three delivery taps located in Cook County, Illinois on Natural's Crawford Line and one delivery tap located in DuPage County, Illinois on Natural's Volo Line, all as more fully set forth in the application on file with the Commission.

Natural states that Northern Illinois Gas Company (NIGAS) is the customer attached to these four delivery points, and it supports their abandonment. Natural also states that there have been no deliveries at any of these points for a number of years.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the

Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8912 Filed 4–15–93; 8:45 am]

BILLING CODE 6717–01–M

[Docket No. CP93–289–000]

Southern Natural Gas Company; Request Under Blanket Authorization

April 12, 1993.

Take notice that on April 7, 1993, Southern Natural Gas Company (Southern), Post Office Box 2563, Birmingham, Alabama 35202–2563, filed in Docket No. CP92–289–000 a request pursuant to section 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to abandon two farm taps located in Mississippi and Alabama, under Southern's blanket certificate issued in Docket No. CP82–406–000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Southern proposes to abandon the Bishop Farm Tap on its South Main Lines in Smith County, Mississippi, because the right-of-way grantor for whom service was intended never constructed connecting facilities to receive gas. Southern proposes to abandon the Dr. Cales Farm Tap on its Bessemer Calera Line in Jefferson County, Alabama, because the Gas Board of the City of Pleasant Grove, which served the customer, has been acquired by Alabama Gas Corporation (Alagasco), which will serve the customer through another existing delivery point. It is stated that no customers will lose service as a result of the proposed abandonment. It is asserted that the one customer being served through the subject facilities has requested the abandonment. It is further asserted that Alagasco's contract demand would not be affected by the abandonment.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93–8911 Filed 4–15–93; 8:45 am]

BILLING CODE 6717–01–M

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–4598–6]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared March 29, 1993 Through April 2, 1993 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities AT (202) 260–5076.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1992 (57 FR 12499).

Draft EISs

ERP No. D–BLM–K60009–CA

Rating EO2, Hidden Valley Resources Residuals Repository, Construction and Operation, Right-of-Way Grants and Conditional Use Permit, San Bernardino County, CA.

SUMMARY: EPA expressed environmental objections based on potential impacts to air and water quality and to wilderness values. EPA recommended that the BLM and San Bernardino County deny the proposed project. EPA requested more information in the FEIS on groundwater monitoring, corrective action, wetlands, biological resources, geology and hydrogeology.

ERP No. DS–FHW–K40183–CA

Rating EO2, Eastern Transportation Corridor (ETC), Construction, Updated Information, CA–231 between the Riverside (CA–91) and Santa Ana Freeways (I–5), Funding and Section 404 Permit, Orange County, CA.

SUMMARY: EPA expressed environmental objections and found the DSEIS to be largely unchanged from the DEIS, which was also rated Environmental Objections. The DSEIS offers additional mitigation for impacts to biological resources, however, most of EPA's original objections still need to be addressed. The DSEIS does not demonstrate that the project purpose of reducing traffic congestion and air emissions will be met. The DSEIS appears to underestimate adverse air quality impacts and does not offer mitigation for exceedances predicted in a nonattainment area.

ERP No. DS–IBR–G32021–NM

Rating EC2, Rio Grande-Velarde to Caballo Dam, Operation and Maintenance, Information on River Maintenance Program, Rio Grande and Middle Rio Grande Project, Elephant Butte Reservoir, MN.

Summary: EPA requested that additional information be provided in the Final EIS on the implementation of mitigation measures.

Final EISs

ERP No. F–AFS–K65142–CA

Southbranch Resource Management Project, Harvest Timber, Road Closures and Developing Water Storage Facilities, Peavine Compartment, Tahoe National Forest, Foresthill Ranger District, Placer County, CA.

Summary: Review of the Final EIS was not deemed necessary. No formal comment letter was sent to the preparing Agency.

ERP No. F–NOA–D90015–DE

Delaware National Estuarine Research Reserve Management Plan, St. Jones River and Blackbird Creek Designation Sites, Implementation and Funding, Kent and New Castle Counties, DE.

Summary: EPA expressed no objections to the project, it does offer numerous pollution prevention opportunities to be considered in developing the reserve.

ERP No. F–SCS–F36153–IN

Muddy Fork of Silver Creek Watershed, Flood Prevention and Watershed Protection, Funding and COE 404 Permit, Clark, Floyd and Washington Counties, IN.

Summary: EPA continued to have environmental objections with the proposed project due to the altering of the hydrology of the floodplain by the stream channelling. Another concern was the lack of adequate mitigation for

adverse impacts to the endangered Indiana bat and the gray bat.

ERP No. F–SFW–K90026–CA

Tijuana Estuary Tidal Restoration Project, Implementation, Tijuana River National Estuarine Research Reserve, Section 10 and 404 Permits and Special Use Permit, San Diego County, CA.

Summary: Review of the Final EIS was not deemed necessary. No formal comment letter was sent to the preparing Agency.

ERP No. FS–COE–E36035–MS

Upper Steele Bayou Flood Control Plan, Updated Information for Proposed Changes to the Unconstructed Portion of the Project, Bolivar, Washington and Greenville Counties, MS.

Summary: EPA's concerns regarding follow-up monitoring and necessary future management of mitigation properties acquired for the losses attendant to this project was addressed.

Dated: April 13, 1993.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 93–8983 Filed 4–15–93; 8:45 am]

BILLING CODE [illegible]

[ER–FRL–4598–5]

Environmental Impact Statements; Availability

Responsible Agency: Office of Federal Activities, General Information (202) 260–5076 or (202) 260–5075. Weekly Receipts of Environmental Impact Statements Filed April 5, 1993 through April 9, 1993 Pursuant to 40 CFR 1506.9.

EIS No. 930117, Draft EIS, FHW, OK, Poteau Bypass Corridor, Construction, US 59/US 271 junction 4.5 Miles to the US 59/OK 112 junction, Funding and COE Section 404 Permit, City of Poteau, LeFlore County, OK, Due: June 1, 1993, Contact: Bruce Lind (405) 231–4725.

EIS No. 930118, Draft EIS, FHW, AZ, Price Freeway (Loop 101) Corridor, Construction, Price Road between the Superstition Freeway to Pecos Road, Funding and Right-of-Way Acquisition, Maricopa County, AZ, *Due:* June 1, 1993, Contact: Ken Davis (602) 379–3646.

EIS No. 930119, Draft EIS, AFS, OR, Paw Timber Sale, Harvest Timber and Road Construction, Implementation, Umpqua National Forest, Diamond Lake Ranger District, Douglas County, OR, Due: June 1, 1993, Contact: Rick Abbott (503) 498–2531.

EIS No. 930120, Draft EIS, FHW, MN, Mankato South Route (Blue Earth C.S.A.H 90) Roadway, Construction, TH 169/TH 60 on the west to TH 83, Funding, Right-of-Way and COE Section 404 Permits, Minnesota, Le Sueur and Blue Earth Rivers, Blue Earth County, MN, Due: June 1, 1993, Contact: James McCarthy (612) 290–3241.

EIS No. 930121, Draft EIS, AFS, MT, Tolan Creek Timber Sale, Harvest Timber and Road Construction, Tolan Creek, Bitterroot National Forest, Sula Ranger District, Ravalli County, MT, Due: June 15, 1993, Contact: David M. Campbell (406) 821–3201.

EIS No. 930122, Draft EIS, AFS, OR, Oregon Dunes National Recreation Area, Amend to Land and Resource Management Plan, Suislaw National Forest, Coos, Douglas and Lane Counties, OR, Due: July 15, 1993, Contact: James R. Furnish (503) 750–7000.

EIS No. 930123, Draft EIS, COE, TX, NM, Roving Sands Joint Training Exercise Program and White Sands Missile Range, Implementation, 11th Air Defense Artillery Brigade, Site Specific, Fort Bliss, El Paso County, TX and Otero and Dona Ana Counties, NM, Due: June 1, 1993, Contact: Arver Ferguson, Jr. (817) 334–3246.

Dated: April 13, 1993.

Richard E. Sanderson,

Director, Office of Federal Activities.

[FR Doc. 93–8984 Filed 4–15–93; 8:45 am]

BILLING CODE 6560–50–U–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry (ATSDR)

[ATSDR–64]

Availability of Final Toxicological Profiles; Correction

A notice announcing the availability of the final versions of 28 of the 30 toxicological profiles in the fourth set of ATSDR's final toxicological profiles was published in the **Federal Register** on March 26, 1993, (58 FR 16410). This notice is corrected as follows:

On page 16410, in the third column, in the twelfth line of the last paragraph, "5258" should read "5285."

On the same page, in the third column, in the fourteenth line of the last paragraph, "1–800–336–4700" should read "1–800–553–6847."

On the same page, in the table, in the eleventh line under the heading NTIS Order No., "PB/93/110752/AS" should read "PB/93/110732/AS" for Toxicological Profile no. 11. Cresols.

Dated: April 12, 1993.

Walter R. Dowdle,

Deputy Administrator, Agency for Toxic Substances and Disease Registry.

Certified To Be a True Copy of the Original.

Carolyn Wilburn,

Certifying Officer.

[FR Doc. 93–8924 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–70–P

Centers for Disease Control and Prevention

CDC Advisory Committee on the Prevention of HIV Infection (CDC ACPHI): Subcommittee on Improving Public Understanding of the HIV Epidemic: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following subcommittee meeting.

Name: CDC ACPHI Subcommittee on Improving Public Understanding of the HIV Epidemic.

Times and Dates: 10 a.m.–7 p.m., May 4, 1993. 8 a.m.–4p.m., May 5, 1993.

Place: CDC, Executive Park Facility, 26 Executive Park Drive, Conference Room A, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available.

Purpose: The initial meeting of this subcommittee will provide subcommittee members with an orientation to the task and a comprehensive overview of CDC's programs to improve public understanding about HIV/AIDS.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Connie Granoff, Committee Assistant, Office of the Associate Director for HIV/AIDS, CDC, 1600 Clifton Road, NE, Mailstop E–40, Atlanta, Georgia 30333, telephone 404/639–2918.

Dated: April 12, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–8928 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–18–M

CDC Advisory Committee on the Prevention of HIV Infection (CDC ACPHI): Subcommittee on Preventing Risk Behaviors Among School Students: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease

Control and Prevention (CDC) announces the following subcommittee meeting.

Name: CDC ACPHI Subcommittee on Preventing Risk Behaviors Among School Students.

Time and Dates: 8:30 a.m.–5 p.m., May 3–4, 1993.

Place: Embassy Suites Hotel-Atlanta Airport, 4700 Southport Road, College Park, Georgia 30349.

Status: Open to the public, limited only by the space available.

Purpose: The initial meeting of this subcommittee will provide subcommittee members with a brief overview of all CDC school health activities related to HIV prevention. The subcommittee will begin planning for the more in-depth review of these activities.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Connie Granoff, Committee Assistant, Office of the Associate Director for HIV/AIDS, CDC, 1600 Clifton Road, NE, Mailstop E–40, Atlanta, Georgia 30333, telephone 404/639–2918.

Dated: April 12, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–8929 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–18–M

Idaho National Engineering Laboratory Environmental Dose Reconstruction Project: Public Meetings

The National Center for Environmental Health (NCEH), Centers for Disease Control and Prevention (CDC), announces the following meetings.

Name: Idaho National Engineering Laboratory Environmental Dose Reconstruction Project.

Date: Monday, May 3, 1993.

Time: 7 p.m.–9 p.m.

Place: Owyhee Plaza Hotel, 1109 Main Street, Boise, Idaho 83702.

Date: Tuesday, May 4, 1993.

Time: 7 p.m.–9 p.m.

Place: Best Western Burley Inn, 800 N. Overland Avenue, Burley, Idaho 83318.

Date: Wednesday, May 5, 1993.

Time: 7 p.m.–9 p.m.

Place: Arco Council Chambers, 140 S. Capital, Arco, Idaho 83405.

Status: Open to the public for observation and comment, limited only by space available. The meeting rooms accommodate approximately 100 people.

Purpose: Under a Memorandum of Understanding with the Department of Energy (DOE), the Department of Health and Human Services has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use.

An initial step in an analytic epidemiologic study for persons living offsite of a given DOE facility is the reconstruction of radiation doses due to releases from that facility. CDC is beginning such an environmental dose reconstruction for DOE's Idaho National Engineering Laboratory near Idaho Falls, Idaho. A contractor has been selected to begin gathering the data necessary to perform the dose reconstruction and to provide for logistics of public involvement in this project. The purpose of these public meetings is to: (1) Demonstrate how the computer database is used to compile all the relevant information; (2) provide the public an opportunity to review actual records that have been entered into the database; and (3) solicit any additional comments from the public regarding the Environmental Dose Reconstruction Project.

Agenda items are subject to change as priorities dictate.

CONTACT PERSON FOR MORE INFORMATION: Leeann Sewell, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia, 30341–3724, telephone 404/488–7040.

Dated: April 12, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination, Centers for Disease Control and Prevention (CDC).

[FR Doc. 93–8930 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–18–M

Food and Drug Administration

Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meeting and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

MEETING: The following advisory committee meeting is announced:

Neurological Devices Panel of the Medical Devices Advisory Committee

Date, time, and place. June 11, 1993, 8 a.m., rm. 100, 1390 Piccard Dr., Rockville, MD.

Type of meeting and contact person. Open committee discussion, 8 a.m. to 10 a.m.; open public hearing, 10 a.m. to 11 a.m., unless public participation does not last that long; open committee discussion, 11 a.m. to 1 p.m.; Robert F. Munzner, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 1390 Piccard Dr., Rockville, MD 20850, 301–427–1044.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to present data, evidence, or arguments must provide this material to the contact person before April 30, 1993, and should include the names and addresses of proposed participants, and an indication of the approximate time required for any oral presentation.

Open committee discussion. The committee will consider data pertaining to intracranial balloon embolization devices and make recommendations to the agency concerning the adequacy of this data as valid scientific evidence.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or

otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, rm. 12A–16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: April 12, 1993.

Jane E. Henney,

Deputy Commissioner for Operations.

[FR Doc. 93–8993 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Services Administration

Final Funding Priority and Special Considerations for Grants for Geriatric Education Centers

The Health Resources and Services Administration (HRSA) announces the final funding priority and special considerations for fiscal year (FY) 1993, Grants for Geriatric Education Centers under the authority of section 777(a) of the Public Health Service Act, as amended by the Health Professions Education Extension Amendments of 1992, Pub. L. 102–408, dated October 13, 1992.

This program was announced in the **Federal Register** at 57 FR 58509 on December 10, 1992. The announcement included a proposed funding priority and two proposed special considerations. A comment period of 30 days was established to allow public comment concerning the proposed funding priority and proposed special considerations. No comments were received. The final funding priority and special considerations remain as proposed.

Final Funding Priority

A funding priority will be given to applications that demonstrate linkages for the purpose of training educators or practitioners who serve minority or low-income elderly. Eligible training sites include Area Health Education Centers, community and migrant health centers, community mental health centers, Native American clinics, Native Hawaiian clinics, state or local health departments, public health clinics, rural hospitals and clinics, and home health agencies and long-term care facilities that accept Medicaid patients. This priority is consistent with a HRSA strategy to improve the geriatric expertise of health professionals who serve minority and low-income elders at risk of poor health outcomes.

Applicants must identify the training facility to be utilized, the number and type of trainees, and the nature and length of the training experience. A letter of agreement that demonstrates an understanding of and commitment to the proposed training activity must be included for each facility.

Final Special Considerations

Special consideration will be given to the extent to which applicants enroll educators and practitioners from underserved areas, for example, rural areas. This special consideration is intended to foster improved geriatric health care in rural and other underserved areas because health professionals who come from such areas are more likely to return there upon completion of training to teach and provide needed health services.

Special consideration will also be given to programs that provide training and continuing education to health care professionals (including allied health professionals) in the delivery of health and long-term care services to persons with Alzheimer's disease. Alzheimer's disease represents one of the most significant medical and social problems of aging. This special consideration encourages activities designed to improve the qualifications of health care professionals who work directly with Alzheimer's Disease patients and families, and who oversee the care provided by formal and informal caregivers.

If additional programmatic information is needed, please contact:

Ms. Anne Kahl, Geriatric Initiatives Branch, Division of Associated, Dental, and Public Health Professions, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, Room 8–103, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–6887.

This program, Grants for Geriatric Education Centers, is listed at 93.969 in the Catalog of Federal Domestic Assistance. It is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100). This program is not subject to the Public Health System Reporting Requirements.

Dated: April 12, 1993.

Robert G. Harman,

Administrator.

[FR Doc. 93–8995 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–15–P–M

Availability of Funds for Grants To Provide Outpatient Early Intervention Services With Respect to HIV Disease

AGENCY: Health Resources and Services Administration.

ACTION: Second correction notice.

In notice document 93–5954 beginning on page 14216 in the issue of Tuesday, March 16, 1993, and subsequent correction notice document 93–7515, published on April 1, 1993, application deadline dates for both competing and noncompeting continuation grants with September 30 budget start dates as well as applications for new grants must be received by the appropriate RGMO by June 18, 1993.

There are no other changes to this notice.

Dated: April 12, 1993.

Robert G. Harmon, M.D., M.P.H.,

Administrator.

[FR Doc. 93–8940 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–15–P

National Institutes of Health

John E. Fogarty International Center for Advanced Study in the Health Sciences; Meeting of the Fogarty International Center Advisory Board

Pursuant to Public Law 92–463, notice is hereby given of the twenty-fourth meeting of the Fogarty International Center (FIC) Advisory Board, May 25, 1993, in the Lawton Chiles International House (Building 16), at the National Institutes of Health.

The meeting will be open to the public from 8:30 a.m. to 2 p.m. The morning agenda will include a report by the Director, FIC; discussion of the President's FY 1994 budget for the FIC; status report of NIH participation in the Human Frontier Science Program; and a report on FIC's Sub-Saharan African initiative.

The afternoon agenda will be a report on the development of FIC's long-range plan.

In accordance with the provisions of secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, the meeting will be closed to the public from 2:30 p.m. to adjournment for the review of applications for International Research Fellowships, Senior International Fellowships, Fogarty International Research Collaboration Awards, International Cooperative Biodiversity Groups, nominations for Scholars-in-Residence award, and proposals for Scholars Conferences.

Myra Halem Committee Management Assistant, Fogarty International Center, Building 31, room B2C08, National Institutes of Health, Bethesda, Maryland 20892 (301–496–1491), will provide a summary of the meeting and a roster of the committee members upon request.

Dr. Coralie Farlee, Assistant Director for International Legislation and Advisory Activities, Fogarty International Center (Executive Secretary), Building 31, room B2C08, telephone 301–496–1491, will provide substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. Halem at least 2 weeks in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.989, Senior International Award Program, and 93.934 Fogarty International Research Collaboration Award)

Dated: April 1, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–8982 Filed 4–15–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Aging; Meeting of the Board of Scientific Counselors

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Scientific Counselors, National Institute on Aging, May 10–11, 1993, to be held at the Gerontology Research Center, Baltimore, Maryland. The meeting will be open to the public on Monday, May 10 from 9 a.m. until 12 noon, and from 1:30 until 5:30 p.m. and again on Tuesday, May 11, from 9 to 11 a.m. and from 12:30 until 3:30 p.m. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sec. 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, the meeting will be closed to the public on May 10 from 12 noon to 1:30 p.m., and from 5 p.m. until recess. On May 11, the meeting will be closed from 11 a.m. until 12:30 p.m., and from 330 p.m. until adjournment for the review, discussion, and evaluation of individual programs and projects conducted by the National Institute on Aging, NIH, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute clearly unwarranted invasion of personal privacy.

Ms. June C. McCann, Committee Management Officer, NIA, Gateway Building, 7201 Wisconsin Avenue, room 2C218, National Institutes of Health, Bethesda, Maryland 20892, (301/496–9322), will provide a summary of the meeting and a roster of committee members upon request.

Dr. George R. Martin, Scientific Director, NIA, Gerontology Research Center, 4940 Eastern Avenue, Baltimore, Maryland 21224, will furnish substantive program information.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: April 2, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–8978 Filed 4–15–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute on Deafness and Other Communication Disorders; Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the following National Institute on Deafness and Other Communication Disorders Special Emphasis Panel.

The meeting will be closed in accordance with the provisions set forth in sec. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications, contract proposals, and/or cooperative agreements. These applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such a patentable material, and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Panel: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel

Date of Meeting: May 12, 1993

Time of Meeting: 8 a.m. until adjournment

Place of Meeting: Bethesda Hyatt, One Metro Center, Bethesda MD

Agenda: Review of proposals received in response to RFP–NIH–NIDCD–DC–93–01, Hereditary Hearing Impairment Resource Registry

Contact Person: Dr. Marilyn Semmes, Scientific Review Administrator, NIDCD/SRB, Executive Plaza South, room 400B, Bethesda, Maryland 20892, (301) 496–8683.

(Catalog of Federal Domestic Assistance Program No. 93.173 Biological Research Related to Deafness and Other Communicative Disorders)

Dated: April 1, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

This is certified to be a true copy.

[FR Doc. 93–8979 Filed 4–15–93; 8:45 am]

BILLING CODE 4140–01–M

National Institute of Diabetes and Digestive and Kidney Diseases; Meeting of Subcommittee B of the Diabetes and Digestive and Kidney Diseases Special Grants Review Committee

Pursuant to Public Law 92–463, notice is hereby given of a meeting of Subcommittee B of the Diabetes and Digestive and Kidney Diseases Special Grants Review Committee, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), on May 27–28, 1993, at the Embassy Suites Hotel, Chevy Chase Pavillion, 4300 Military Road, NW., Washington, DC 20015. This meeting will be open to the public on May 27 from 8 a.m. to 8:15 a.m. to

discuss administrative details or other issues relating to committee activities. Attendance by the public will be limited to space available. Notice of the meeting rooms will be posted in the hotel lobby.

In accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, the meeting will be closed to the public on May 27 from 8:15 a.m. to recess and May 28 from 8 a.m. to adjournment for the review, discussion and evaluation of individual research grant applications. Discussion of these applications could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mrs. Winnie Martinez, Committee Management Officer, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Building 31, room 9A19, Bethesda, Maryland 20892, 301–496–6917, will provide a summary of the meeting and a roster of the committee members upon request.

For any further information, and for individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, please contact the Scientific Review Administrator, Dr. Francisco Calvo, (301) 496–7697. In addition please note, if you are requesting special assistance, you must do so two weeks prior to the meeting date.

(Catalog of Federal Domestic Assistance Program No. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: April 1, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–8980 Filed 4–15–93; 8:45 am]

BILLING CODE 4145–01–M

National Library of Medicine; Meetings of the Board of Regents and Subcommittee

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Board of Regents of the National Library of Medicine on May 26–27, 1993, in the Board Room of the National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland. The Extramural Programs Subcommittee will meet on May 25 in the 5th-floor Conference Room, Building 38A, from 2 p.m. to approximately 3:30 p.m., and will be closed to the public.

The meeting of the Board will be open to the public from 9 a.m. to approximately 4:30 p.m. on May 26 and from 9 a.m. to adjournment on May 27 for administrative reports and program discussions. Attendance by the public will be limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Mrs. Karin Colton at 301–496–4621 two weeks before the meeting.

In accordance with provisions set forth in secs. 552b(c)(4), 552b(c)(6), title 5, U.S.C. and sec. 10(d) of Public Law 92–463, the entire meeting of the Extramural Programs Subcommittee on May 25 will be closed to the public, and the regular Board meeting on May 26 will be closed from approximately 4:30 p.m. to adjournment for the review, discussion, and evaluation of individual grant applications. These applications and the discussion could reveal confidential trade secrets or commercial property, such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Mr. Robert B. Mehnert, Chief, Office of Inquiries and Publications Management, National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland 20894, Telephone Number: 301–496–6308, will furnish a summary of the meeting, rosters of Board members, and other information pertaining to the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.879—Medical Library Assistance, National Institutes of Health)

Dated: April 1, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93–8981 Filed 4–15–93; 8:45 am]

BILLING CODE 4140–01–M

Public Health Services

Announcement of Application Deadlines for Fiscal Year 1993 for Selected Programs of the Bureau of Primary Health Care

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Advance notice of application deadline dates for Fiscal Year 1993.

SUMMARY: The Health Resources and Services Administration's Bureau of Primary Health Care (BPHC) expects to provide funding for new and competing renewal grant applications during fiscal year 1993 for the programs listed below. The purpose of this announcement is to give early notice to potential applicants of funding amounts and application deadlines.

FOR FURTHER INFORMATION CONTACT: Potential applicants may contact the appropriate individual as indicated below for application information. (See Appendix).

SUPPLEMENTARY INFORMATION: A notice of Availability of Funds will be published in the **Federal Register** for each of the programs identified below, announcing program provisions, priorities, and evaluation criteria.

Set forth below is the information for each of the identified BPHC's programs:

Program authority	Application deadlines	Estimated number of awards	Estimated amounts available	Grants management contact point (see appendix)
- Community Health Centers (Sec. 330 of the PHS Act).	June 1, 1993			Appropriate RGMO.
• New Starts and Expansions		40–50	$15.7 million	
• Planning Grants		10–12	$.5 million	
- Migrant Health Program (Sec. 329 of the PHS Act).	June 1, 1993			Appropriate RGMO.
• New Starts and Expansions		10	$1.8 million	
- Public Housing Primary Health Care (Sec. 340A of the PHS Act).	June 15, 1993			Appropriate RGMO.
• New		3–5	$1.7 million	
• Expansion		Up to 7	$1.0 million	

Program authority	Application deadlines	Estimated number of awards	Estimated amounts available	Grants management contact point (see appendix)
Outpatient Early Intervention Services with respect to HIV Disease[1] (Secs. 2651–55 of the PHS Act).	Subject to the enactment date of a supplemental appropriation.	.....	.....	Appropriate RGMO.
• New Starts	.....	17	$5.5 million	
• Expansions	.....	90	$12.0 million	
• Special Initiatives	.....	15	$7.5 million	
- State Demonstration Grants for Community Scholarship programs (Sec. 338L of the PHS Act).	July 1, 1993	.....	.....	Central Office GMO.
• New Starts	.....	3–5	$120,000	
- National Health Service Corps Loan Repayment Program (Sec. 338B of the PHS Act).	September 1, 1993	495	$41.3 million	Gerald Anderson 301–443–0743.
- State Loan Repayment Program (Sec. 338I of the PHS Act).	July 1, 1993	19 competing 3–5 new ..	$3.9 million	Central Office GMO.
- Nursing Education Loan Repayment (Sec. 846 of the PHS Act).	September 1, 1993	225	$2,025 million	Gerald Anderson 301–443–0743.
- Pacific Basin Health (Sec. 301 of the PHS Act).	July 1, 1993	Up to 15	$860,000	Appropriate RGMO.

RGMO=Regional Grants Management Officer.
GMO=Grants Management Officer.
[1] Subject to the availability of funds under a fiscal year 1993 supplemental appropriation.

Dated: April 12, 1993.

Robert G. Harmon,

Administrator.

Appendix

Grants Management Officers

Central Office: Alice Thomas, Grants Management Officer, Bureau of Primary Health Care, 12100 Parklawn Drive, Rockville, MD 20857, (301) 443–5902

Region I: Mary O'Brien, Grants Management Officer, PHS Regional Office I, John F. Kennedy Federal Building, Boston, MA 02203, (617) 565–1482

Region II: Steven Wong, Grants Management Officer, PHS Regional Office II, Room 3300, 26 Federal Plaza, New York, NY 10278, (212) 264–4496

Region III: Martin Brea, Acting Grants Management Officer, PHS Regional Office III, P.O. Box 13716, Philadelphia, PA 19101, (215) 596–6653

Region IV: Wayne Cutchens, Grants Management Officer, PHS Regional Office IV, Room 1106, 101 Marietta Tower, Atlanta, GA 30323, (404) 331–2597

Region V: Lawrence Poole, Grants Management Officer, PHS Regional Office V, 105 West Adams Street, 17th Floor, Chicago, IL 60603, (312) 353–8700

Region VI: Joyce Bailey, Grants Management Officer, PHS Regional Office VI, 1200 Main Tower, Dallas, TX 75202, (214) 767–3885

Region VII: Michael Rowland, Grants Management Officer, PHS Regional Office VII, Room 501, 601 East 12th Street, Kansas City, MO 64016, (816) 426–5841

Region VIII: Susan Jaworowski, Grants Management Officer, PHS Regional Office VIII, 1961 Stout Street, Denver, CO 80294, (303) 844–4461

Region IX: Al Tevis, Grants Management Officer, PHS Regional Office IX, 50 United Nations Plaza, San Francisco, CA 94102, (415) 556–2595

Region X: James Tipton, Grants Management Officer, PHS Regional Office X, Mail Stop RX 20, 2201 Sixth Avenue, Seattle, WA 98121, (206) 553–7997.

[FR Doc. 93–8994 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–15–P

Special Project Grants and Cooperative Agreements; Maternal and Child Health Services; Federal Set-Aside Program

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice of availability of funds.

SUMMARY: The Maternal and Child Health Bureau (MCHB), HRSA, announces that fiscal year (FY) 1993 funds are available for grants and cooperative agreements for the following activities: Maternal and Child Health (MCH) Special Projects of Regional and National Significance (SPRANS), including special MCH improvement projects which contribute to the health of mothers, children, and children with special health care needs (CSHCN); MCH research and training; genetic disease testing, counseling and information services; and hemophilia diagnostic and treatment centers. Awards will be made under the program authority of section 502(a) of the Social Security Act, the MCH Federal Set-Aside Program.

Of the approximately $98.4 million available for SPRANS activities in FY 1993, about $27 million will be available to support approximately 238 new and competing renewal projects at an average of $113,000 per award for one year under the MCH SPRANS Federal Set-Aside Program. The remaining funds will be used to support continuation of existing SPRANS projects. The actual amounts available for awards and their allocation may vary, depending on unanticipated program requirements and the volume and quality of applications. Awards are made for grant periods which generally run from 1 up to 5 years in duration. Funds for the MCH Federal Set-Aside Program are appropriated by Public Law 102–394. The regulation implementing the Federal Set-Aside Program was published in the March 5, 1986, issue of the **Federal Register** at 51 FR 7726 (42 CFR part 51a).

The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of Healthy People 2000, a PHS-led national activity for setting priority areas. The MCH Block Grant Federal Set-Aside Program addresses issues related to the Healthy People 2000 objectives of improving maternal, infant, child and adolescent health and developing service systems for children at risk of chronic and disabling conditions. Potential applicants may obtain a copy of Healthy People 2000 (Full Report: Stock No. 017–001–00474–0 or Healthy People 2000 (Summary Report; Stock No. 017–001–00473–1) through the Superintendent of Documents, Government Printing Office Washington, DC 20402–9325, (telephone: 202 783–3238).

ADDRESSES: Grant applications for the MCH SPRANS Federal Set-Aside Program must be obtained from and submitted to: Chief, Grants Management Branch, Office of Program Support, Maternal and Child Health Bureau, Health Resources and Services Administration, Room 18–12, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443–1440. Applicants for research projects will use Form PHS 398, approved by the Office of Management and Budget (OMB) under control number 0925–0001. Applicants for training projects will use Form PHS 6025–1, approved by OMB under control number 0915–0060. Applicants for all other projects will use application Form PHS 5161–1 with revised facesheet DHHS Form 424, approved by OMB under control number 0937–0189. Requests should specify the category or categories of activities for which an application is requested so that the appropriate forms, information and materials may be provided.

DATES: Potential applicants are invited to request application packages for the particular program category in which they are interested, and to submit their applications for funding consideration. Deadlines for receipt of applications differ for the several categories of grants and cooperative agreements. These deadlines are as follows:

MCH Federal Set-Aside Grant and Cooperative Agreements Anticipated Deadline, Award, Funding, and Project Period Information, by Category, FY 1993

Funding source category	Application deadline	Estimated number of awards	Estimated amounts available	Project period
(1) Grants in the following areas:				
1.1 Research	Cycle 1: May 4, 1993 Cycle 2: August 2, 1993	Up to 20	$2.5 million	Up to 5 years.
1.2 Training.				
1.2.1 Long term	May 3, 1993	Up to 35	$4.5 million	Up to 5 years.
1.2.2 Continuing education	July 1, 1993	Up to 30	$500,000	Up to 3 years.
1.3 Genetic disease testing, counseling and information.	May 7, 1993	Up to 7	$1.7 million	3 years.
1.4 Special MCH improvement projects (MCHIP) of regional and national significance in the following areas:				
1.4.1 Maternal, infant, child, and adolescent health.	June 8, 1993	Up to 18	$2.0 million	Up to 3 years, except as noted.
1.4.2 State systems development initiative.	June 22, 1993	Up to 59	$5.9 million	2–3 years.
1.4.3 CSHCN habilitative services priorities.	May 11, 1993	5–10	$1.5 million	Up to 4 years.
1.4.4 Hemophilia center/title V collaboration.	May 14, 1993	2	$100,000	2–3 years.
1.4.5 Comprehensive hemophilia treatment center grants.	June 4, 1993	Up to 30	$4.9 million	3 years.
1.4.6 Data utilization	June 15, 1993	3	240,000	Up to 3 years.
1.4.7 Healthy tomorrows partnership for children.	May 28, 1993	Up to 5	$250,000	5 years.
1.4.8 Field-initiated projects	July 1, 1993	10–15	$500,000	Up to 5 years.
(2) Cooperative agreements (MCHIPs) in the following areas:				
2.1 CSHCN policy and program coordination.	May 11, 1993	1	Up to $500,000	4 years.
2.2 Comprehensive hemophilia cooperative agreements.	May 14, 1993	Up to 3	$2 million	Up to 4 years.

Competing applications will be considered to be on time if they are either:

(1) Received on or before the deadline date, or

(2) Postmarked on or before the deadline date and received in time for orderly processing. (Applicants should request a legibly dated receipt from a commercial carrier or U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

Late applications not accepted for processing or those sent to an address other than specified in the **ADDRESSES** section will be returned to the applicant.

FOR FURTHER INFORMATION CONTACT: Requests for technical or programmatic information should be directed to: Audrey H. Nora, M.D., M.P.H., Director, Maternal and Child Health Bureau, HRSA, room 18–05, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Requests for category-specific technical information should be directed to the contact persons identified below for each category covered by this notice. Requests for information concerning business management issues should be directed to: John Gallicchio, Grants Management Officer (GMO), Maternal and Child Health Bureau, at the address specified in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION: To facilitate the use of this announcement, information in this section has been organized, as outlined in the Table of Contents below, into a discussion of: Program Background, Special Concerns, Overall Review Criteria, SPRANS Program, and Eligible Applicants. In addition, discussion of the SPRANS program is divided into specific funding categories and sub-categories and for each category and sub-category, information is presented under the following headings:

- Application Deadline
- Purpose

- Priorities
- Grants/Amounts
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4.2.1 Category: Children with Special Health Care Needs Policy and Program Coordination
4.2.2 Category: Comprehensive Hemophilia Cooperative Agreements
5. Eligible Applicants
6. Public Health System Reporting Requirements
7. Executive Order 12372

1. Program Background and Objectives

Under Section 502 of the Social Security Act, as amended by the Omnibus Budget Reconciliation Act (OBRA) of 1989, 12.75 percent of amounts appropriated for the Maternal and Child Health Services Block Grant in excess of $600 million are retained by the Secretary of Health and Human Services (HHS) for special Community Integrated Service Systems projects under Section 501(a)(3) of the Act. Of the remainder of the total appropriation, 15 percent of the funds are to be retained by the Secretary to support (through grants, contracts, or otherwise) special projects of regional and national significance, research, and training with respect to maternal and child health and children with special health care needs (including early intervention training and services development); for genetic disease testing, counseling, and information development and dissemination programs; for grants (including funding for comprehensive hemophilia diagnostic treatment centers) relating to hemophilia without regard to age; and for the screening of newborns for sickle cell anemia, and other genetic disorders and follow-up services. The MCH SPRANS set-aside was established in 1981. Support for projects covered by this announcement will come from these SPRANS funds.

2. Special Concerns

In its administration of the MCH Services Block Grant, the MCHB places special emphasis on improving service delivery to women and children from culturally identifiable populations who have been disproportionately affected by barriers to accessible care. This means that SPRANS projects are expected to serve and appropriately involve in project activities members of ethnoculturally distinct groups, unless there are compelling programmatic or other justifications for not doing so. The MCHB's intent is to ensure that project outcomes are of benefit to culturally distinct populations and to ensure that the broadest possible representation of culturally distinct and historically underserved groups is supported through programs and projects sponsored by the MCHB.

Projects supported under SPRANS are expected to be part of community-wide, comprehensive initiatives, to reflect appropriate coordination of primary care and public health activities, and to target HRSA resources effectively to fill gaps in the Nation's health system for at-risk mothers and children. This applies especially to projects in the 15 communities in the Nation which have received grants from HRSA under the Healthy Start initiative. Grantees in these communities providing services related to activities of a Healthy Start program are expected to coordinate their projects with the Healthy Start program efforts. Healthy Start communities include: Aberdeen Area Indian Nations, NE/ND/SD; Baltimore, MD; Birmingham, AL; Boston, MA; Chicago, IL; Cleveland, OH; Detroit, MI; Lake County, IN; New Orleans, LA; New York, NY; Oakland, CA; Philadelphia, PA; Pittsburgh, PA; PeeDee Region, SC; Washington, DC.

3. Criteria for Review and Funding

Consistent with the statutory mandate and with special emphasis on improving service delivery to women and children from culturally distinct populations, the Secretary will review applications for funds under the specific project categories in section 4 as competing applications and will fund those which will, in the Secretary's judgment, best address achievement of the Healthy People 2000 objectives related to maternal, infant, child and adolescent health and service systems for children at risk of chronic and disabling conditions, and otherwise best promote improvements in maternal and child health.

3.1. General Criteria

The Secretary has adopted the criteria specified below, as pertinent, for reviewing and evaluating applications for awards under all SPRANS grants and cooperative agreement project categories announced in this notice. Further guidance in this regard will be supplied in application guidance materials.

—The quality of the project plan or methodology.
—The need for the services, research, training or technical assistance.
—The cost-effectiveness of the proposed project relative to the number of persons proposed to be benefitted, served or trained, considering, where relevant, any special circumstances associated with providing care or training in various areas.
—The extent to which the project will contribute to the advancement of MCH and/or CSHCN services.
—The extent to which rapid and effective use of grant funds will be made by the project.
—The effectiveness of procedures to collect the cost of care and service from third-party payment sources (including government agencies) which are authorized or under legal obligation to make such payment for any service (including diagnostic, preventive and treatment services).
—The extent to which the project will be integrated with the administration of the Maternal and Child Health Services block grants, State primary care plans, public health, and prevention programs, and other related programs in the respective State(s).
—The soundness of the project's management, considering the qualifications of the staff of the proposed project and the applicant's facilities and resources.
—The extent to which the project gives special emphasis to improving service delivery to women and children from culturally identifiable populations who have been disproportionately affected by barriers to accessible care and ensures that members of culturally distinct groups are appropriately represented in the

activities of approved grants and cooperative agreements.
—In communities with Healthy Start projects, a commitment by applicants whose projects are related to activities of a Healthy Start program to coordinate their projects with Healthy Start program efforts.
—The strength of the project's plans for evaluation.

3.2. Approved Applications Funding Criteria

The following mechanisms, as defined below, may be applied in determining scores for ranking the funding of approved applications.
—Funding Preferences—Funding of a specific category or group of approved applications ahead of other categories or groups of applications, such as competing continuation projects ahead of new projects.
—Funding Priorities—Merit reviewers will assign scores based on the extent to which applicants address program priorities specified in this notice for the category in which the application is made.
—Special Considerations—Merit reviewers will assign scores based on the extent to which applicants address special areas of concern.

4. Special Categories of Regional and National Significance

Project categories for SPRANS awards are grouped in this notice under two sections: Grants and Cooperative Agreements.

4.1. Grants

Four major categories of SPRANS grants are discussed below: Research; Training; Genetic Disease Testing, Counseling and Information; and Maternal and Child Improvement Projects (in nine sub-categories):

4.1.1. Category: Research

• Application Deadline: May 4 and August 2, 1993.

• Purpose: To encourage research in maternal and child health which has the potential for ready transfer of findings to health care delivery programs.

• Priorities: Priority will be given to projects which offer the greatest potential for applicability for providing health and related services for mothers and children. Special consideration will be given to projects which address: disparities in health status among population groups; adolescents; health access; and primary care.

By statute, research grants may be made only to public or nonprofit institutions of higher learning and public or nonprofit private agencies and organizations engaged in research or in maternal and child health or programs for CSHCN.

• Grants/Amounts: About $2.5 million will be available to support up to 20 new and competing renewal research projects at an average of $125,000 per award for one year. Project periods are up to 5 years.

• Contact: For programmatic or technical information, contact Gontran Lamberty, Dr. P. H., telephone: 301 443–2190.

4.1.2. Category: Training

Training projects are announced in two sub-categories: Long Term Training and Continuing Education.

4.1.2.1. Sub-category: Long Term Training

• Application Deadline: May 3, 1993.

• Purpose: To support and strengthen MCH programs through long term training of health professionals at the graduate and postgraduate levels, with a special focus on family-centered, community-based care. The programs are designed to develop leadership personnel to provide for comprehensive health, including health promotion and disease prevention, and related services to mothers and children and to address special issues, such as HIV; injury; minority health concerns; and substance abuse. Training is provided to a wide range of health professionals who serve mothers and children. All disciplines are competed on a rotating basis.

Priorities: Disciplines scheduled for competition for the MCH long term training program in FY 1993 are those in the following categories:
—Nursing, especially for nurse practitioners and certified nurse midwives.
—Nutrition.
—University Affiliated Programs (in mental retardation).

By statute, training grants may be made only to public or nonprofit private institutions of higher learning.

• Grants/Amounts: About $4.5 million will be available to support up to 35 new and competing renewal long term training projects in the listed priority areas. Grant awards in different priority areas vary between $45,000-$400,000 for one year. Project periods are up to 5 years.

• Contact: For programmatic and technical information, contact Elizabeth Brannon, M.S., R.D., telephone: 301 443–2190.

4.1.2.2. Sub-category: Continuing Education.

• Application Deadline: July 1, 1993.

• Purpose: To support and strengthen MCH programs through short term, non-degree related training of health professionals and others providing health and related services for mothers and children; workshops; seminars; institutes; and other related activities intended to develop or improve standards, practices or delivery of health care for the MCH population.

• Priorities: Priority in this category will be given to projects in the following areas:
—Collaborative Office Rounds.
—Skills Development.
—Adolescent Access.
—Mentor Training.
—Curriculum Development.
—General.

Preference for funding will be given to projects in the Collaborative Office Rounds category.

By statute, training grants may be made only to public or nonprofit private institutions of higher learning.

• Grants/Amounts: About $500,000 will be available to support up to 20 new and up to 10 competing renewal continuing education training projects, at an average of $25,000 per award for one year. Project periods are up to 3 years.

• Contact: For programmatic or technical information, contact Elizabeth Brannon, M.S., R.D., telephone: 301 443–2190.

4.1.3. Category: Genetic Disease Testing, Counseling and Information

• Application Deadline: May 7, 1993.

• Purpose: To increase access to effective genetic information, education, testing and counseling services.

• Priorities: Priority in the genetic services program is given to projects in the areas of:
—Council of regional networks for genetic services.
—Regional genetic services networks.
—Nationwide blood lead and erythrocyte protoporphyrin (EP) proficiency testing program.
—Alliance of genetic support groups.

• Grants/Amounts: About $1.7 million will be available to support up to 7 competing renewal projects, one in each priority, except for the regional genetic services networks priority area in which one award will be made to each of four regions identified in program guidance. An average of $243,000 per award for one year is anticipated. Project periods are generally 3 years.

• Contact: For programmatic or technical information, contact: Jane S. Lin-Fu, M.D., telephone: 301 443–1080.

4.1.4. Category: Maternal and Child Health Improvement Projects

Maternal and Child Health Improvement Projects (MCHIP) are divided into 8 sub-categories: Maternal, Infant, Child, and Adolescent Health; State Systems Development Initiative; Children with Special Health Care Needs Habilitative Services Priorities; Hemophilia Center/Title V Collaborative Systems Demonstrations; Comprehensive Hemophilia Treatment Centers; Data Utilization and Enhancement; Healthy Tomorrows Partnerships for Children and Field-Initiated Projects.

4.1.4.1. Sub-category: Maternal, Infant, Child, and Adolescent Health

- Application Deadline: June 8, 1993.
- Purpose: To improve the health of all mothers, infants, children, and adolescents. Demonstration projects in this category contribute to the reduction of infant mortality and morbidity and the improvement of maternal and infant health. Child and adolescent health projects enhance the health of children, adolescents, and their families through prevention of violence and unintentional injuries and development of resources for improving access to health care and health and health outcomes for children and youth.
- Priorities: Priority in this MCHIP category will be given to projects in the following program areas:

—Improving the rates of obstetrical provider participation in health programs for women who are inadequately served.
—Supporting intense home visitation follow-up programs for infants and families at high medical or social risk, as described in Title V of the ADAMHA Reorganization Act (Public Law 102–321).
—Supporting planning grants for mobile perinatal outreach program. These are one year grants.
—Developing or upgrading of community standards for health and safety in family child care settings.
—Improving the health status and enhancing health service for adolescents and children with particular concern for the health and development of the black male child.
—Establishing a national information clearinghouse to facilitate the exchange of information concerning all Federal research and initiatives relating to adolescent health and facilitating access to this information. This is a five year project.

- Grants/Amounts: About $2.0 million will be available to support up to 18 new and competing renewal projects in the primary/preventive services for women and children MCHIP category, for priority and other projects, at an average of $111,000 per award for one year. Project periods are up to 3 years except where noted for a specific priority.
- Contact: For programmatic or technical information, contact David Heppel, M.D., telephone: 301–443–2250.

4.1.4.2. Subcategory: State Systems Development Initiative

- Application Deadline: June 22, 1993.
- Purpose: To assist State Agency MCH and CSHCN programs in (a) the development and implementation of an infrastructure that (b) shows results in establishing community-based service systems to meet the health and health related needs of all children and their families and that (c) addresses the physical, psychological, and social aspects of health care. The service system should be collaborative, family-centered, community-based, culturally competent, care-coordinated, comprehensive, universal, accessible, and developmentally oriented.
- Priorities: Priority in this MCHIP category will be given to projects which show evidence of the following elements:

—A conceptualization for system building that embodies the system characteristics outlined above.
—Assurance of joint State MCH and CSHCN Agency participation.
—A collaborative process at the State level which is broadly based and established as an infrastructure designed to endure beyond the termination of targeted Federal funding.
—The likelihood of the project to produce progress toward a statewide array of community-based service systems.
—System development activity relates to all three dimensions of health—physical, psychological, and social.
—Coordination of project activities with MCH Block Grant and CISS activities (as appropriate).
—In addition, for previous SSDI grantees the degree to which past system development activity relates to future plans.

Preference for funding will be given to joint applications from State MCH and CSHCN programs. Applications from State Agency MCH and CSHCN programs must be jointly developed and intended for joint implementation. All States and jurisdictions not already, receiving funds under the the FY 1992 project grant program, "Support for the Development of a Comprehensive Care System of Services for All Children," are encouraged to apply. Grantees currently receiving such funds must apply under this subcategory for additional competing supplemental support of up to $50,000 per year above their second year and third year projected continuation levels to cover the cost of expanding the scope of their system building to encompass CSHCN as well as MCH interests.

- Grants/Amounts: Up to $5.9 million will be available to support up to 59 new and competing renewal projects in the special State MCH program development activities MCHIP category at an average of $100,000 per award for one year. Project periods are up to 3 years for new applications and up to 2 years for supplemental applications.
- Contact: For programmatic or technical information on MCH issues, contact David Heppel, M.D., telephone: 301 443–2250; on CSHCN issues, contact John Shwab, telephone: 301 443–2370.

4.1.4.3. Sub-category: Children With Special Health Care Needs Habilitative Services Priorities

- Application Deadline: May 11, 1993.
- Purpose: To improve community-based maternal and child health, education, and social systems to assure that CSHCN and their families who require targeted efforts receive high quality services in comprehensive systems which promote healthy growth and development, support integration into community life, and expand and enhance linkages at the Federal, State and local levels between public and private sectors and among all levels of care.
- Priorities: Priority in this MCHIP category will be given to projects in the following program areas:

—Family-professional collaboration, which define and facilitate collaborative relationships between families of CSHCN and the public and private professional sectors at the community level.
—Financing/cost control, which demonstrate a financing rationale for providing preventive, primary, and specialty health care and services for CSHCN and their families at the community level.
—Early intervention services, which: (1) improve integration, collaboration, and continuity with various federally funded programs, especially Healthy Start, Community Integrated Service System projects, and the Healthy Children/Ready to Learn initiative; or (2) study racial, ethnic,

socioeconomic, cultural, and service resource variables which influence the provision of early intervention services needed by families of young children with special health care needs and develop innovative strategies for providing access to data and other information. Preference for funding under this priority will be given to applications from parent coalitions in collaboration with public and private agencies interested in improving methods for insuring family access to and the utilization of information.

—Adolescent health/transitional systems, which address the transition of adolescents with special health care needs to adult-based care and services and link together local and State agency programs, vocational rehabilitation, special education, and the business community.

—Service delivery systems for chronic illness, which develop a comprehensive systems approach to the delivery of health care and services for children with specific chronic illnesses and their families, assuring linkages between tertiary care and community resources; and providing for the development of a community-based system of followup services.

Special consideration will be given to approved projects based on the extent to which applicants address priority areas of concern.

• Grants/Amounts: About $1.5 million will be available for all priority areas in this MCHIP category, to support 1–2 new projects in each at an average cost of $150,000. Applicants will compete for funding with other proposals in their program area, but there are no amounts reserved for any individual program area. The project period is up to 4 years.

• Contact: For programmatic and technical information, contact John Shwab, telephone: 301 443–2370.

4.1.4.4. Subcategory: Hemophilia Treatment Center Network/State Collaborative Systems Demonstrations.

• Application Deadline: May 14, 1993.

• Purpose: To demonstrate ways in which hemophilia treatment centers can work collaboratively with State Title V programs that enhance the capability of and/or the development of statewide systems of care.

• Priorities: Priorities in this category are as follows:

—Consortia building for the development of statewide health care systems which include hemophilia.

—Enhancement of existing models which allow for the inclusion of hemophilia care into statewide systems of care.

—Development of new models which recognize community based/oriented projects for developing statewide systems of care.

Preference for funding will be given to existing hemophilia diagnostic and treatment centers which show evidence of one or more of the following:

—Participation in existing consortia, or collaboration and integration of hemophilia into State Title V programs funded under the MCH Services Block Grant.

—Strong potential for consortia building or establishing program linkages, or inclusion of hemophilia in State Title V program planning.

—Unserved and/or underserved hemophilia populations.

• Grants/Amounts: About $100,000 under the MCH–SPRANS set-aside will be available to support 2 new projects at an average of $50,000 per award for 1 year. The project period is up to 3 years.

• Contact: For programmatic or technical information, contact Sharon Barrett, M.S., telephone: 301–443–9051.

4.1.4.5. Sub-category: Comprehensive Hemophilia Treatment Centers

• Application Deadline: June 4, 1993.

• Purpose: To expand the capability of comprehensive hemophilia treatment centers to provide: (1) regional services to support hemophilia comprehensive treatment centers; (2) diagnostic and treatment services to persons with hemophilia and other congenital bleeding disorders; and (3) HIV preventive, medical and psychosocial support services to individuals with hemophilia, their sexual partners and families.

• Priorities: Priority in this MCHIP category will be given to the following activities identified as overall hemophilia program goals:

—Fostering development of comprehensive care systems that provide culturally sensitive, family-centered care, coordinated through a system of regional hemophilia centers.

—Increasing access of persons with hemophilia and their families to comprehensive care services.

—Emphasizing prevention within the comprehensive care system to reduce complications and morbidity associated with hemophilia and preventing new cases of HIV infection in sexual partners of persons with hemophilia.

—Improving long-term outcomes of HIV-infected individuals with hemophilia and their infected sexual partners and offspring by treating their morbidity at the earliest stage, utilizing the full range of available comprehensive care services, e.g., infectious disease treatment, nutrition, mental health, dental, and drug treatment.

—Ensuring delivery of high quality care at the appropriate level of care, with an emphasis on ambulatory care services that may reduce unnecessary hospital stays, and absence from work and school.

—Sustaining comprehensive care systems for persons with hemophilia through appropriate mechanisms.

Preference for funding will be given to hemophilia treatment centers currently supported by MCHB.

• Grants/Amounts: Approximately $4.9 million under the MCH–SPRANS set-aside will be available for the funding of hemophilia treatment centers. Up to 30 projects will be supported at an average of $163,000 per award. The project period is 3 years.

• Contact: For programmatic or technical information, contact Sharon Barrett, M.S., telephone: 301–443–9051.

4.1.4.6. Sub-category: Data Utilization and Enhancement

• Application Deadline: June 15, 1993.

• Purpose: To enable Federal, State, and local MCH/CSHCN agencies, in collaboration with State primary care planning, to develop data and data systems required under Title V that facilitate needs assessment, planning, monitoring or evaluation of maternal and child agencies and comprehensive health services.

• Priorities: Priority in this MCHIP category will be given to projects in the areas identified below:

—Enhancement of data collection and analysis capabilities of State and local health agencies.

—Compilation of new data and development and application of analytic techniques regarding the health status of and delivery of comprehensive health care to mothers and children.

—Networking, coordination, and integration of existing and proposed resources and data and analysis systems developed in other States or organizations, including but not limited to the State Public Health Reporting System operated by the Public Health Foundation.

Special consideration will be given to competing continuations which

demonstrate local health agencies' ability to use available data or need for MCH program development, monitoring and evaluation.

• Grants/Amounts: An estimated $240,000 will be available to support three competing renewal projects. Project periods are up to 3 years.

• Contact: For programmatic or technical information, contact Russ Scarato, telephone: 301 443–2340.

4.1.4.7. Sub-category: Healthy Tomorrows Partnerships for Children.

• Application Deadline: May 28, 1993.

• Purpose: To support projects for children that improve access to health services and utilize preventive strategies. The initiative encourages additional support from the private sector and from foundations to form community-based partnerships to coordinate health resources for pregnant women, infants and children.

• Priorities: Priority in this MCHIP category will be given to projects in the areas identified below.

—Local initiatives that are community-based, family-centered, comprehensive and culturally relevant and improve access to health services for infants, children, adolescents, or CSHCN.

—Evidence of a capability to meet cost participation targets by securing funds required for the second and sequential years in an amount not less than 66.7 percent of the total budget.

In the interest of equitable geographic distribution, preference for funding will be given to projects from States without a currently funded project in this category.

• Grants/Amounts: About $250,000 will be available to support up to 5 new Healthy Tomorrows projects, at an average of $50,000 per award for one year. The project period is 5 years.

• Contact: For programmatic or technical information, contact Latricia Robertson, telephone: 301 443–3163.

4.1.4.8. Sub-category: Field-Initiated Projects

• Application Deadlines: July 1, 1993.

• Purpose: To support projects of high priority that are so time sensitive that they cannot be delayed for submission against normal MCHB category deadlines. Applications must be accompanied by a letter explaining why the proposed project is so time sensitive that the application cannot be submitted against normal MCHB category deadlines. Applications submitted under this category may not be under consideration under any other category during FY 1993. Research applications are not supportable under this sub-category. Staff of MCHB will be the final arbiter of the acceptability of special project applications for review. Prospective applicants are urged to submit their letters of explanation and an abstract of the project well in advance of submitting their formal applications, so that the work of proposal development can be avoided if the proposed project is judged as inappropriate for submission under this category.

• Grants/Amounts: About $500,000 will be available to support 10 to 15 new and competing continuation special projects. Project periods are up to 5 years.

• Contact: Advance letters of explanation should be submitted to the Chief, Grants Management Branch, or to the appropriate Division Director: Director, Division of Maternal, Infant, Child and Adolescent Health, telephone: 301 443–2251; or Director, Division of Services for CSHCN, telephone: 301 443–2350; or Director, Division of Systems, Education, and Science, telephone: 301 443–2340. The address for each of them is: Maternal and Child Health Bureau, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857.

4.2. Cooperative Agreements

It is anticipated that substantive Federal programmatic involvement will be required in the cooperative agreements described below. Federal involvement will include planning, guidance, coordination and participation in programmatic activities. Periodic meetings, conferences, and/or communications with the award recipient will be held to review mutually agreed upon goals and objectives and to assess progress.

Additional details on the degree of Federal programmatic involvement will be included in the program guidance for cooperative agreement applications.

Cooperative agreements are discussed below in two categories: Children with Special Health Care Needs Policy and Program Coordination; and Comprehensive Hemophilia Cooperative Agreements.

4.2.1 Category: Children with Special Health Care Needs Policy and Program Coordination

• Application Deadline: May 11, 1993.

• Purposes: To support one project which will: (1) provide a forum for interaction between MCHB in its efforts on behalf of CSHCN and broader CSHCN policy initiatives by coordinating and capitalizing upon the critical mass of existing knowledge and skills in the field; (2) establish a strategy to enhance communication between the MCHB and organizations representing leaders and policy makers concerned with CSHCN; and (3) assist in the development and dissemination of information concerning a variety of issues relevant to CSHCN and their families.

• Priorities: Priority in this cooperative agreement category will be given to the activities identified below:

—Support and enhancement of cooperation and coordination among agencies, programs and initiatives serving CSHCN.

—Implementation and oversight of various communication activities concerning CSHCN, e.g., telecommunications, distant learning, and alternative approaches to information dissemination.

—Provision of technical assistance and consultation to Federal, State, and local public and private entities concerning a broad range of activities related to CSHCN.

—Development and implementation of information exchange concerning a variety of special health care needs, policies, and programmatic issues.

For this category, funding preference will be given to public or private agencies or institutions of higher learning with expertise and documented experience in policy and programmatic issues related to CSHCN.

• Grants/Amounts: Up to $500,000 will be available to support one cooperative agreement. The project period is 4 years.

• Contact: For programmatic and technical information, contact John Shwab, telephone: 301 443–2370.

4.2.2 Category: Comprehensive Hemophilia Cooperative Agreements

• Application Deadline: May 14, 1993.

• Purposes: To support projects which serve as resource centers or centers of excellence for: (1) the conduct of technical assistance and consultation; (2) input into policy development studies; and (3) the development and dissemination of information and educational materials on hemophilia. Projects would assist the MCHB-sponsored hemophilia treatment centers, hemophilia peer based support groups or chapters, MCHB block grant programs, and other MCHB grant recipients as appropriate to foster communication, collaboration and linkages at the national and local levels.

• Priorities: Priority in this cooperative agreement category will be given to the following activities identified as overall hemophilia program goals in sub-category 4.1.4.5. above.

• Special consideration in this category will be given to existing public or not for profit organizations which have demonstrated expertise in hemophilia and demonstrate an ability to meet current program priorities for the hemophilia community at large.

• Grants/Amounts: Approximately $2 million will be available to support up to 3 new hemophilia cooperative agreements. Project periods are up to four years, depending upon the negotiated scope of work.

• Contact: For programmatic or technical information, contact Sharon Barrett, M.S., telephone: 301 443–9051.

Time does not permit consideration in this project cycle of comments from the public on the categories, priorities, special considerations and preferences described above. Any comments which members of the public wish to make should be submitted to: Chief, Grants Management Branch, at the address listed in the ADDRESSES section. They will be taken into consideration when priorities are developed for the next solicitation.

5. Eligible Applicants

The statute at section 502(a)(2) provides that training grants may be made only to public or nonprofit private institutions of higher learning and that research grants may be made only to public or nonprofit private institutions of higher learning and public or nonprofit private agencies and organizations engaged in research in maternal and child health or programs for CSHCN. Any public or private entity, including an Indian tribe or tribal organization (as defined at 25 U.S.C. 450b), is eligible to apply for grants or cooperative agreements in all other program categories.

6. Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements (approved under OMB No. 0937–0195). Under these requirements, the community-based nongovernmental applicant must prepare and submit a Public Health System Impact Statement (PHSIS). The PHSIS is intended to provide information to State and local health officials to keep them apprised of proposed health services grant applications submitted by community-based nongovernmental organizations within their jurisdictions.

Community-based nongovernmental applicants are required to submit the following information to the head of the appropriate State and local health agencies in the area(s) to be impacted no later than the Federal application receipt due date:

(a) A copy of the face page of the application (SF 424).

(b) A summary of the project (PHSIS), not to exceed one page, which provides:

(1) A description of the population to be served.

(2) A summary of the services to be provided.

(3) A description of the coordination planned with the appropriate State and local health agencies.

7. Executive Order 12372

The MCH Federal set-aside program has been determined to be a program which is not subject to the provisions of Executive Order 12372 concerning intergovernmental review of Federal programs.

The OMB Catalog of Federal Domestic Assistance number is 93.110.

Dated: January 27, 1993.

Robert G. Harmon,

Administrator.

[FR Doc. 93–8941 Filed 4–15–93; 8:45 am]

BILLING CODE 4160-15-P

Social Security Administration

Agency Forms Submitted to the Office of Management and Budget for Clearance

Normally on Fridays, the Social Security Administration publishes a list of information collection packages that have been submitted to the Office of Management and Budget (OMB) for clearance in compliance with Public Law 96–511, The Paperwork Reduction Act. The following clearance packages have been submitted to OMB since the last list was published in the **Federal Register** on March 19, 1993. (Call Reports Clearance Officer on (410) 965–4142 for copies of package.)

1. Enumeration Identity Review Data Collection Form—0960–NEW. The information on form SSA–38 will be used by the Social Security Administration to evaluate the accuracy and efficiency of policies and procedures used to assign Social Security numbers. It may also help determine if further study is needed in specific areas of this process. The respondents will be selected applicants for social security numbers.

Number of Respondents: 300
Frequency of Response: 1
Average Burden Per Response: 30 minutes
Estimated Annual Burden: 150 hours

2. Report(s) of Student Beneficiary at End of School Year—0960–0089. The information on forms SSA–1388–C2, SSA–1388–U2 and SSA–1388–C1–FC is used by the Social Security Administration to verify a student's full-time attendance at an approved educational institution. The affected public consists of claimants or beneficiaries who are students and are requested to provide this information.

Number of Respondents: 200,000
Frequency of Response: 1
Average Burden Per Response: 10 minutes
Estimated Annual Burden: 33,333 hours

3. Final Regulation Concerning Medicaid Use Report—0960–0267. The information required by this regulation is used by the Social Security Administration to determine if an individual is entitled to special Supplemental Security Income (SSI) payments. The respondents are SSI recipients whose payments were stopped based on earnings.

Number of Respondents: 25,000
Frequency of Response: 1
Average Burden Per Response: 3 minutes
Estimated Annual Burden: 1,250 hours
OMB Desk Officer: Laura Oliven

Written comments and recommendations regarding these information collections should be sent directly to the appropriate OMB Desk Officer designated above at the following address: OMB Reports Management Branch, New Executive Office Building, room 3208, Washington, DC 20503.

Dated: April 9, 1993.

Nicholas E. Tagliareni,

Section Chief for Review, Design and Development, Social Security Administration.

[FR Doc. 93–8905 Filed 4–15–93; 8:45 am]

BILLING CODE 4190-29-M

Substance Abuse and Mental Health Administration

Suspension of a Laboratory Which No Longer Meets Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services routinely publishes in the **Federal Register** a list of laboratories currently certified to meet standards of

subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (53 FR 11986) dated April 11, 1988. This notice informs the public that, effective April 8, 1993, the following laboratory's certification is suspended:

Eagle Forensic Laboratory, Inc., 950 North Federal Highway, Suite 308, Pompano Beach, FL 33062, 305-946-4324.

FOR FURTHER INFORMATION CONTACT: Division of Workplace Programs, Substance Abuse and Mental Health Services Administration, room 9A–54, Telephone: 301–443–6014, 5600 Fishers Lane, Rockville, Maryland 20857.

Dated: April 13, 1993.

Elaine M. Johnson,

Acting Administrator, SAMHSA.

[FR Doc. 93–9041 Filed 4–15–93; 8:45 am]

BILLING CODE 4160–20–U

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

[Docket No. N–93–1917; FR–3350–N–27]

Federal Property Suitable as Facilities to Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

ADDRESSES: For further information, contact James N. Forsberg, room 7262, Department of Housing and Urban Development, 451 Seventh Street SW., Washington, DC 20410; telephone (202) 708–4300; TDD number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 56 FR 23789 (May 24, 1991) and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration*, No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Judy Breitman, Division of Health Facilities Planning, U.S. Public Health Service, HHS, room 17A–10, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 56 FR 23789 (May 24, 1991).

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to James N. Forsberg at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (i.e., acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *U.S. Navy:* John J. Kane, Deputy Division Director, Dept. of Navy, Real Estate Operations, Naval Facilities Engineering Command, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–0474; *GSA:* Leslie Carrington, Federal Property Resources Services, GSA, 18th and F Streets NW., Washington, DC 20405; (202) 208–0619; *Dept. of Transportation:* Ronald D. Keefer, Director, Administrative Services & Property Management, DOT, 400 Seventh St. SW., room 10319, Washington, DC 20590; (202) 366–4246; *Dept. of Interior:* Lola D. Knight, Property Management Specialist, Dept. of Interior, 1849 C St. NW., Mailstop 5512–MIB, Washington, DC 20240; (202) 208–4080; (These are not toll-free numbers).

Dated: April 9, 1993.

Don I. Patch,

Acting Deputy Assistant Secretary for Grant Programs.

Title V, Federal Surplus Property Program Federal Register Report for 4/16/93

Suitable/Available Properties

Buildings (by State)

Pennsylvania

Bldg. 1, Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310008
Status: Excess
Base closure
Number of Units: 1
Comment: Approx 300,000 sq. ft., 15 story, concrete/brick frame, pres of asbestos, needs rehab, 36.6 acres of improved land incs. tennis court, parking & roads, sched to be vacated 3/94

3 Enlisted Quarters
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310009

Status: Excess
Base closure
Number of Units: 3
Comment: 6464–8418 sq. ft., 2/3 story, concrete/brick frame, presence of asbestos, needs rehab, scheduled to be vacated 3/94, elig. for nomination to Natl Register of Historic Places

5 Officer's Quarters
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310010
Status: Excess
Base closure
Number of Units: 5
Comment: 1888–11582 sq. ft., 2 story, concrete/brick frame, presence of asbestos, needs rehab, scheduled to be vacated 3/94, elig. for nomination to Natl Register of Historic Places

16 Administrative Bldgs.
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310011
Status: Excess
Base closure
Number of Units: 16
Comment: 6000–25250 sq. ft., ½ story, concrete/brick frame, needs rehab, pres. of asbestos, sched to be vacated 3/94, incs. offices/chapel/classrooms, elig for Natl Reg of Hist Places

9 Support Bldgs.
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310012
Status: Excess
Base closure
Number of Units: 9
Comment: 150–6528 sq. ft., 1 story concrete/brick frame, needs rehab, pres. of asbestos, sched to be vacated 3/94, incs. storage bldgs/garages/sheds, elig for Natl Reg of Hist Place

6 Sentry Shelters
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310013
Status: Excess
Base closure
Number of Units: 6
Comment: 28–896 sq. ft., 1 story, concrete/brick frame, needs a roof, pres. of asbestos, sched to be vacated 3/94, incs. sentry house/shelters, elig for Natl Reg of Historic Places

4 Support Bldgs.
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310014
Status: Excess
Base closure
Number of Units: 4
Comment: 5162–14756 sq. ft., 1 story, concrete/brick frame, presence of asbestos, roof needs replacement, sched to be vacated 3/94, incs. maint. shop, bowling alley, phys. therapy bldg

3 Secured Bldgs.
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310015
Status: Excess
Base closure
Number of Units: 3
Comment: 8637–15566 sq. ft., 1 story, concrete/brick frame, presence of asbestos, needs major rehab, scheduled to be vacated 3/94, most recent use—storage

6 Utility Structures
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310016
Status: Excess
Base closure
Number of Units: 6
Comment: 196–6172 sq. ft., 1 story, concrete/brick frame, presence of asbestos, needs rehab, scheduled to be vacated 3/94, incs. sewage/water pump houses, elec substations, heat plant

Staff Lounge
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310017
Status: Excess
Base closure
Number of Units: 1
Comment: 4164 sq. ft., 1 story, concrete/brick frame, presence of asbestos, scheduled to be vacated 3/94

Bldg. 8, Warehouse
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310018
Status: Excess
Base closure
Number of Units: 1
Comment: 10558 sq. ft., 3 story, concrete/brick frame, roof needs replacement, presence of asbestos, scheduled to be vacated 3/94

Land (by State)

California

Folsom South Canal
SW corner of Whiterock Rd. & Folsom S Canal
Rancho Cordova Co: Sacramento CA 95670–
Landholding Agency: Interior
Property Number: 619310002
Status: Excess
Comment: 1.52 acres; perpetual easement over .25 acre, surrounding land use is commercial

Pennsylvania

North East Plot (K13)
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310019
Status: Excess
Base closure
Number of Units: 1
Comment: 2 paved parking areas, paved roads, (approx. 9.5 acres), scheduled to be vacated 3/94

North West Plot (K12)
Former Naval Hospital
1701 Pattison Avenue
Philadelphia PA 19145–5199
Landholding Agency: Navy
Property Number: 779310020
Status: Excess
Base closure
Number of Units: 1
Comment: 2 paved parking lots, paved roads, (2.7 acres), scheduled to be vacated 3/94

Unsuitable Properties

Buildings (by State)

Alaska

Bldg. R1, Holiday Beach
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310014
Status: Unutilized
Reason: Secured Area

Bldg. S–3
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310015
Status: Unutilized
Reason: Secured Area

Bldg. S–16
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310016
Status: Unutilized
Reason: Secured Area

Bldg. 82
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310017
Status: Unutilized
Reason: Secured Area

Bldg. 86
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310018
Status: Unutilized
Reason: Secured Area

Bldg. 98
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310019
Status: Unutilized
Reason: Secured Area

Bldg. 524A
U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310020
Status: Unutilized
Reason: Within airport runway clear zone. Secured Area

Bldg. 624

U.S. Coast Guard Support Center
Kodiak Co: Kodiak Island AK 99619–5014
Landholding Agency: DOT
Property Number: 879310071
Status: Unutilized
Reason: Within airport runway clear zone. Secured Area

Land (by State)

Kentucky

Artemus Site
Across Cumberland River Bridge
Artemus Co: Knox KY
Landholding Agency: GSA
Property Number: 549320001
Status: Excess
Reason: Within 2000 ft. of flammable or explosive material. Floodway
GSA Number: 4–Z–KY–602

[FR Doc. 93–8767 Filed 4–15–93; 8:45 am]
BILLING CODE 4210–29–M

Office of Fair Housing and Equal Opportunity

[Docket No. N–93–3558; FR–3428–N–03]

Task Force on Occupancy Standards in Public and Assisted Housing

AGENCY: Office of the Assistant Secretary for Fair Housing and Equal Opportunity, HUD.

ACTION: Notice of Location of Subcommittee Meetings.

SUMMARY: The Task Force on Occupancy Standards in Public and Assisted Housing was established on December 31, 1992 in accordance with the provisions of section 643 of the Housing and Community Development Act of 1992 (P.L. 102–550) and the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). The Task Force's charter was published in the **Federal Register** on January 7, 1993 at 58 FR 3039. The Task Force was created to review all rules, policy statements, handbooks, and technical assistance memoranda issued by the Department on the standards and obligations governing residency in public and assisted housing and to make recommendations to the Secretary for the establishment of reasonable criteria for occupancy. The Task Force has established an Executive Committee and three additional subcommittees—Admissions, Occupancy and Evictions. This is a notice announcing the location of meetings for the subcommittees of the Task Force.

FOR FURTHER INFORMATION CONTACT: Laurence D. Pearl, Office of Fair Housing and Equal Opportunity, room 5226, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410. Telephone: (202) 708–3727, (TDD) (202) 708–0113. (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION: Notice of the following meetings was published in the **Federal Register** on February 25, 1993 at 58 FR 11415.

Tues., Apr. 20, 9 a.m. to 5 p.m., Admissions
Wed., Apr. 21, 9 a.m. to.5 p.m., Occupancy
Thurs., Apr. 22, 9 a.m. to 12 noon, Evictions
Thurs., Apr. 22, 1 p.m. to 5 p.m., Executive

These meetings will be held at the Hall of States, 444 North Capitol Street, NW., room 283, Washington, DC. Please note that the starting time for the Admissions Committee has been changed to 9 a.m.

AGENDA: The Admissions, Occupancy and Evictions Subcommittee meetings will consider drafts prepared by their members regarding the Department's occupancy standards in public and assisted housing, and develop proposals to be considered by the full Task Force, circulated to the public and considered at public hearings. The Executive Committee will recommend the time, place and logistics for the public hearings and make such other recommendations to the full Task Force as may be appropriate.

PUBLIC PARTICIPATION: These are open meetings. The public is also invited to submit written comments on any aspect of the Task Force's mandate or activities to Ms. Bonnie Milstein, the Chair of the Task Force, at 1101 Fifteenth Street, NW., suite 1212, Washington, DC 20005–2765.

Dated: April 9, 1993.

Bonnie Milstein,

Chair, Task Force on Occupancy Standards in Public and Assisted Housing.

Roy Rodriguez,

Acting General Deputy Assistant Secretary for Fair Housing and Equal Opportunity.

[FR Doc. 93–8939 Filed 4–15–93; 8:45 am]
BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–921–03–4120–03; NDM 81582]

Request for Public Comment on Environmental Analysis, Fair Market Value and Maximum Economic Recovery

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management requests public comment on the fair market value of certain coal resources it proposes to offer for competitive lease sale.

The land included in Coal Lease Application NDM 81582 is located in Mercer County, North Dakota, and is described as follows:

T. 145 N., R. 86 W., 5th P.M.

Sec. 6: Lots 3, 4, 5, SE¼NW¼
Sec. 8: E½E½, NW¼NW¼, SE¼NW¼, SE¼SW¼, SW¼SE¼
Sec. 18: E½.

792.900 acres.

The Beulah bed, averaging 11.5 feet in thickness, is the only economically minable coal seam within the tract. The tract contains an estimated 7.6 million short tons of recoverable lignite. Coal quality, as received, averages 6919 BTU/lb, 36.1 percent moisture, 6.2 percent ash, 0.8 percent sulfur, 30.5 percent fixed carbon, and 27.3 percent volatile matter. This coal bed is being mined in adjoining tracts by the Coteau Properties Company.

The public is invited to submit written comments on the environmental analysis, fair market value, and the maximum economic recovery of the tract.

In addition, notice is also given that a public hearing will be held on Friday, May 21, 1993, on the environmental assessment, the proposed lease sale, the fair market value, and maximum economic recovery of the proposed lease tract.

DATES: Comments must be received on or before May 21, 1993. The public hearing will be held at 1 p.m., Mountain Daylight Time on the same date, at the BLM Dickinson District Office, 2933 Third Avenue West, Dickinson, North Dakota.

ADDRESSES: For more complete data on this tract, please contact Donald Gilchrist (telephone 406–255–2816), Bureau of Land Management, Montana State Office, 222 North 32nd Street, P.O. Box 36800, Billings, Montana 59107 or Douglas Burger (telephone 701–225–9148), Bureau of Land Management, Dickinson District Office, 2933 Third Avenue West, Dickinson, North Dakota 58601. Copies of the environmental assessment are available at both addresses.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Coal Management regulations 43 CFR parts 3422 and 3425, not less than 30 days prior to publication of a notice of sale, the Secretary shall solicit public comments on the environmental assessment, the proposed sale, fair

market value, and maximum economic recovery on the proposed lease tract. Proprietary data marked as confidential may be submitted to the Bureau of Land Management in response to this solicitation of public comments. Data so marked shall be treated in accordance with the laws and regulations governing the confidentiality of such information. A copy of the comments submitted by the public on fair market value and maximum economic recovery, except those portions identified as proprietary by the author and meeting exemptions stated in the Freedom of Information Act, will be available for public inspection at the Bureau of Land Management, 222 North 32nd Street, Billings, Montana during regular business hours (9 a.m. to 4 p.m.) Monday through Friday.

Comments should be sent to the Bureau of Land Management, P.O. Box 36800, Billings, Montana 59107 and should include, but not necessarily be limited to the following:

1. The quality and quantity of the coal resources;

2. The mining method or methods which would achieve maximum economic recovery of the coal including specification of the seams to be mined, timing and rate of production, restriction to mining, and inclusion of the tract in an existing mining operation;

3. The fair market value appraisal including but not limited to the evaluation of the tract as an incremental unit of an existing mine, selling price of the coal, mining and reclamation costs, net present value discount factors, depreciation and other tax accounting factors, value of the surface estate, and any comparable sales data of similar coal lands.

The values given above may or may not change as a result of comments received from the public and changes in market conditions between now and when final economic evaluations are completed.

Dated: April 9, 1993.

Robert H. Lawton,

State Director.

[FR Doc. 93–8925 Filed 4–15–93; 8:45 am]

BILLING CODE 4310-DN-M

[UT–040–03–4830–01–ADVB]

Cedar City District Advisory Council Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of a meeting of the Cedar City District Advisory Council.

SUMMARY: Notice is hereby given in accordance with Public Law 92–463 of a meeting of the Cedar City District Advisory Council. Agenda Items will include issues directly related to the development and preparation of the Dixie Resource Management Plan.

DATES: May 20–21, 1993. The meeting will begin at 10 a.m. at the Dixie Resource Area Office, 225 North Bluff, St. George, Utah and end mid-afternoon of May 21, 1993.

FOR FURTHER INFORMATION CONTACT: District Manager Gordon R. Staker, Cedar City District Office, 176 East D.L. Sargent Drive, Cedar City, Utah 84720. Telephone: 801–586–2401.

SUPPLEMENTARY INFORMATION: Advisory Council Meetings are open to the public. Interested persons may make oral statements or file written statements for the Board's consideration. Anyone wishing to make a statement notify the District Manager by Monday, May 17, 1993. A time limit may be established by the District Manager. Anyone wishing to attend the meeting will need a four-wheel drive vehicle and a lunch for both days of the meeting.

Dated: April 9, 1993.

Gordon R. Staker,

District Manager.

[FR Doc. 93–8897 Filed 4–15–93; 8:45 am]

BILLING CODE 4310-DQ-M

[NV–930–03–4210–05;N–50827]

Notice of Realty Action

ACTION: Change of use for an existing lease/purchase for recreation and public purposes Clark County, NV.

SUMMARY: The following described public land in Las Vegas, Clark County, Nevada was classified as suitable for lease/purchase on July 11, 1985, for public library purposes (N–36901) by Las Vegas/Clark County Library District, under the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 et seq.). It is now intended to modify the classification to allow it for use as a public park, under the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 et seq.). The City of Las Vegas intends to use the land for the extension of a public park, (W. Wayne Bunker Family Park).

Mount Diablo Meridian, Nevada

T. 20 S., R. 60 E.,

Sec. 10: NE¼NE¼NE¼NW¼.

Aggregating 2.5 acres (gross).

The land is not required for any federal purpose. The lease/purchase is consistent with current Bureau planning for this area and would be in the public interest. The lease and/or patent, when issued, will be subject to the provisions of the Recreation and Public Purposes Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States, Act of August 30, 1890, 26 Stat. 391, 43 U.S.C. 945.

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

and will be subject to:

1. An easement 40 feet in width along the east boundary and 50 foot width along the north boundary in favor of the City of Las Vegas for streets, roads, public utilities and flood control purposes in accordance with the transportation plan for the City of Las Vegas.

2. Those rights for power line purposes which have been granted to Nevada Power Company by Permit No. Nev–061618 under the Act of March 4, 1911.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Las Vegas District, 4765 W. Vegas Drive, Las Vegas, Nevada.

Upon publication of this notice in the **Federal Register**, the above described land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease/purchase under the recreation and public purposes act, leasing under the mineral leasing laws and disposal under the mineral disposal laws.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Las Vegas District, P.O. Box 26569, Las Vegas, Nevada 89126. Any adverse comments will be reviewed by the State Director.

In the absence of any adverse comments, the classification of the lands described in this Notice will become effective 60 days from the date of publication in the **Federal Register**. The lands will not be offered for lease/purchase until after the modification of the classification becomes effective.

Dated: April 7, 1993.

Ben F. Collins,

District Manager, Las Vegas, NV

[FR Doc. 93–8888 Filed 4–15–93; 8:45 am]

BILLING CODE 4310-HC-M

[NV–930–03–4210–05; N–57141]

Notice of Realty Action Purchase for Recreation and Public Purposes (R&PP) Act, Clark County, NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Purchase of public lands in Clark County.

SUMMARY: The following described public land in Clark County, Nevada, has been identified and examined and found suitable for purchase for recreational or public purposes under the provisions of the R&PP Act, as amended (43 U.S.C. 869 et seq.). Clark County proposes to use the land for solid waste transfer stations.

Mount Diablo Meridian, Nevada

T. 13 S., R. 70 E. (Bunkerville),
Sec. 35: NW¼NW¼NE¼SW¼.
T. 14 S., R. 66 E. (Moapa/Glendale),
Sec. 36: SW¼SW¼SW¼SW¼.
T. 16 S., R. 56 E. (Indian Springs),
Sec. 16: S½NE¼NW¼NE¼.
T. 16. S, R. 68 E. (Overton/Logandale),
Sec. 6: SE¼SE¼SW¼SW¼.
T. 21 S., R. 60 E. (Las Vegas—Flamingo/Durango),
Sec. 16: S½SW¼SE¼SW¼, SE¼SE¼SW¼SW¼.
T. 22 S., R. 61 E. (Las Vegas—Shelbourne),
Sec. 17: N½N½NE¼SW¼NE¼.
T. 24 S., R. 58 E. (Goodsprings),
Sec. 25: E½SW¼NE¼SW¼.
T. 25 S., R. 57 E. (Sandy Valley),
Sec. 05: NW¼NW¼SW¼SE¼.
T. 28 S., R. 63 E. (Searchlight),
Sec. 27: portion of lots 1 and 2.

Containing 32.5 acres more or less.

Three of the parcels, or portions thereof, described above were previously segregated and classified for lease/purchase under the R&PP Act as follows:

1. T. 14 S., R. 66E., sec. 36: SW¼SW¼SW¼SW¼ (Moapa/Glendale), classified for the Glendale Town Equipment Storage site on 11/24/86.

2. T. 21 S., R. 60 E., sec. 16: S½SW¼SE¼SW¼, SE¼SE¼SW¼SW¼ (Las Vegas—Flamingo/Durango), classified for a public park on 9/25/86.

3. T. 22 S., R. 61 E., sec. 17: N½NE¼NE¼SW¼NE¼ (Las Vegas—Shelbourne), classified for a transfer station on 9/28/75.

This NORA will modify the above classifications to allow for disposal for transfer stations under the R&PP Act.

The land is not required for any federal purpose. The purchase is consistent with the current Bureau planning for this area and would be in the public interest. The patent, when issued, will be subject to the provisions of the R&PP Act and applicable regulations of the Secretary of the Interior, and will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States. Act of August 30, 1890 (43 U.S.C. 945).

2. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

and will be subject to:

1. An easement for streets, roads, public utilities and flood control purposes in accordance with the transportation plan for Clark County/the City of Las Vegas.

2. Those rights for water pipeline which have been granted to the Las Vegas Valley Water District by grant no. N–47834 under the Act of October 21, 1976, in the La Vegas—Shelbourne parcel.

3. Those rights for a highway which have been granted to the Nevada Department of Transportation by grant no. CC–020583 under the Act of November 09, 1921, in the Goodsprings parcel.

4. Those rights for an access road and powerline which have been granted to MCI Telecommunications Corporation by grant no. N–41362 under the Act of October 21, 1976, in the Goodsprings parcel.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Las Vegas District, 4765 W. Vegas Drive, Las Vegas, Nevada.

Upon publication of this notice in the **Federal Register**, the above described land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for purchase under the recreation and public purposes act, leasing under the mineral leasing laws and disposals of mineral materials.

For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested parties may submit comments to the District Manager, Las Vegas District, P.O. Box 26569, Las Vegas, Nevada 89126. Any adverse comments will be reviewed by the State Director.

In the absence of any adverse comments, the classification of the land described in this Notice will be come effective 60 days from the date of publication in the **Federal Register**. The land will not be offered for purchase until after the classification becomes effective.

Dated: March 30, 1993.

Mason K. Hall,

Acting District Manager, Las Vegas, NV.

[FR Doc. 93–8889 Filed 4–15–93; 8:45 am]

BILLING CODE 4310–HC–M

Fish and Wildlife Service

Wild Bird Conservation Act (Act) of 1992; Prohibition on the Import of Certain Species of Exotic Birds to the United States, Based on Quotas

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: *Prohibition based on Importation Quotas:* The U.S. Fish and Wildlife Service (Service) is notifying the public that, for certain species of exotic birds listed in the Appendices to the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the importation quota pursuant to the Wild Bird Conservation Act of 1992 has been met, and no more birds of that species can be imported into the United States in the absence of further administrative action by the Service. *Corrections to quota:* The Service is notifying the public of corrections to the importation quota for two species.

ADDRESSES: Comments and information should be sent to: Director, U.S. Fish and Wildlife Service, c/o Mr. Marshall P. Jones, Chief, Office of Management Authority, 4401 N. Fairfax Dr., room 432, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Dr. Susan S. Lieberman, Office of Management Authority, at the above address, telephone (703) 358–2093.

SUPPLEMENTARY INFORMATION: On October 23, 1992, the President signed into law the Wild Bird Conservation Act of 1992 (Act), the purposes of which include promoting the conservation of exotic birds by: Ensuring that all imports into the United States of species of exotic birds are biologically sustainable and not detrimental to the species; ensuring that imported birds are not subject to inhumane treatment; and assisting wild bird conservation and management programs in countries of origin. On December 4, 1992, the Service published a Notice in the **Federal Register** announcing the effects of the Act, including the implementation of an importation quota for all species of exotic birds (as defined by the Act) listed in any Appendices to CITES. The **Federal Register** notice of December 4, 1992, listed the importation quotas for each species covered by the Act.

Pursuant to section 105(d), "Limitation on Number Imported During First Year," the Act directs the Secretary to prohibit the importation into the United States of the following species of exotic birds listed in the Appendices to CITES, for which the statutorily-defined quota has been met or exceeded:

Agapornis pullaria
Ara macao
Aratinga canicularis
Balaeniceps rex
Barnardius barnardi
Cacatua leadbeateri
Cacatua tenuirostris
Columba livia
Corythaeola cristata
Falco biarmicus
Forpus coelestis
Forpus passerinus
Neopsittacus musschenbroekii
Otus leucotis
Poicephalus senegalus
Psittacula longicauda
Purpureicephalus spurius
Pyrrhura picta
Uraeginthus bengalus

Therefore, the Service hereby prohibits the importation of the exotic birds enumerated above, subject to future administrative action under sections 106, 107, or 112 of the Act.

The Service notes that the quota for *Columba livia* does not include the domesticated subspecies *C. livia domestica*, which in the view of the Service is not subject to the provisions of the Act.

Pursuant to section 106 of the Act ("List of Approved Species"), the aforementioned species and those prohibited as per the **Federal Register** notice of December 4, 1992, cannot be imported into the United States unless they are placed on a list of approved species or approved breeding facilities, or unless a permit is issued under section 112 of the Act. The Service published a Notice of Intent to promulgate regulations in the **Federal Register** of December 4, 1992, which includes regulations to promulgate the aforementioned list of approved species. No species can be placed on an approved list, nor can permits be issued for exemptions authorized under the Act, until those regulations are promulgated.

In addition, the Service hereby corrects the quota for the species *Amazona aestiva*. In the **Federal Register** notice of December 4, 1992, no quota was published for the species, since it is banned from export from all countries of origin. However, since 3,937 individuals of the species were imported in 1991, a quota of 3,937 exists for the species (until October 22, 1993), for those individual birds being exported or re-exported from countries other than the countries in which species is found in the wild.

In addition, the Service hereby corrects an error from the **Federal Register** notice of December 4, 1992, which published a quota for *Lorius garrulus*, even though imports of that species are prohibited under the Act. There is no quota for the species *Lorius garrulus*.

Author: The primary author of this notice is Dr. Susan S. Lieberman, U.S. Fish and Wildlife Service, Office of Management Authority.

Dated: April 8, 1993.

Richard N. Smith,

Acting Director.

[FR Doc. 93–8850 Filed 4–15–93; 8:45 am]

BILLING CODE 4310-55-M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–550 (Final)]

Sulfur Dyes From India

Determination

On the basis of the record [1] developed in the subject investigation, the Commission determines, pursuant to section 735(b) of the Tariff Act of 1930 (19 U.S.C. 1673d(b)) (the Act), that an industry in the United States is not materially injured or threatened with material injury, and the establishment of an industry in the United States is not materially retarded, by reason of imports from India of sulfur dyes, including sulfur vat dyes, [2] provided for in subheadings 3204.15, 3204.19.30, 3204.19.40, and 3204.19.50 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce to be sold in the United States at less than fair value (LTFV).

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Sulfur dyes are synthetic organic coloring matter containing sulfur. Sulfur dyes are obtained by high temperature sulfurization of organic material containing hydroxy, nitro, or amino groups, or by reaction of sulfur or alkaline sulfide with aromatic hydrocarbons. For purposes of this investigation, sulfur dyes include, but are not limited to, sulfur vat dyes with the following color index numbers: Vat Blue 42, 43, 44, 45, 47, 49, and 50 and Reduced Vat Blue 42 and 43. Sulfur vat dyes also have the properties described above. All forms of sulfur dyes are covered, including the reduced (leuco) or oxidized state, presscake, paste, powder, concentrate, or so-called "pre-reduced, liquid ready-to-dye" forms.

Background

The Commission instituted this investigation effective October 23, 1992, following a preliminary determination by the Department of Commerce that imports of sulfur dyes, including sulfur vat dyes, from India were being sold at LTFV within the meaning of section 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the institution of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of November 12, 1992 (57 FR 53779). The hearing was held in Washington, DC, on January 13, 1993, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determination in this investigation to the Secretary of Commerce on April 12, 1993. The views of the Commission are contained in USITC Publication 2619 (April 1993), entitled "Sulfur Dyes from India: Determination of the Commission in Investigation No. 731–TA–550 (Final) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigation."

Issued: April 12, 1993.

By order of the Commission.

Paul R. Bardos,

Acting Secretary.

[FR Doc. 93–8922 Filed 4–15–93; 8:45 am]

BILLING CODE 7020-02-P

INTERSTATE COMMERCE COMMISSION

Intent To Engage in Compensated Intercorporate Hauling Operations

This is to provide notice as required by 49 U.S.C. 10524(b)(1) that the named corporations intend to provide or use compensated intercorporate hauling operations as authorized in 49 U.S.C. 10524(b).

(A) Parent corporation and address of principle office: Philip Morris Companies Inc., (a Virginia corporation), 120 Park Avenue, New York, NY 10017.

(1) Primary contact relative to CIH services: Private Truck Operations, Kraft General Foods, Inc., Three Lakes Drive, Northfield, IL 60093–2753.

(B) Wholly owned subsidiaries which will participate in the operations, and states of incorporation:

(1) Abdulla of Bond Street, Ltd., Delaware
(2) Argintina Holdings Inc., Delaware

(3) B. Muratti Sons & Company Inc., New York
(4) BEVACQ Corporation, Missouri
(5) Bennett, Farr & Wells Bottling Co., Michigan
(6) Boboli Co., Delaware
(7) BOR Services Inc., Delaware
(8) Bouyea-Fassetts, Inc., Delaware
(9) Capri Sun, Inc., Delaware
(10) Carolina Properties of Greenville Inc., South Carolina
(11) Charles Freihofer Baking Co., Inc., New York
(12) Churny Company, Inc., Delaware
(13) Colonial Heights Packaging, Inc., Delaware
(14) Dart Resorts Inc., Delaware
(15) Di Giorno Foods Co., Delaware
(16) Eastern Projects, Inc., California
(17) Entenmann's, Inc., Delaware
(18) Entenmann's Frozen Foods, Inc., Florida
(19) Filter Materials Ltd., Delaware
(20) Foodco Corporation (10%), California
(21) Gardners Good Foods, Inc., New Jersey
(22) General Foods Bakery Companies, Inc., Delaware
(23) General Foods Borinquen Inc., Delaware
(24) General Foods Capital Corporation, Delaware
(25) General Foods Credit Corporation, Delaware
(26) General Foods Credit Investors No. 1 Corporation, Delaware
(27) General Foods Credit Investors No. 2 Corporation, Delaware
(28) General Foods Credit Investors No. 3 Corporation, Delaware
(29) General Foods Manufacturing Corporation of Mexico, Delaware
(30) Grant Holdings, Inc., Pennsylvania
(31) HAG GF Vertriebs & Marketing Corporation, Delaware
(32) HNB Investment Corp., Delaware
(33) Highland Mutual Water Company, Colorado
(34) Highlands Ranch Decorator Center, Inc., Colorado
(35) Highlands Ranch Development Corp., Colorado
(36) Highlands Ranch Escrow Company, Inc., Colorado
(37) Highlands Ranch Estates, Inc., Colorado
(38) Highlands Ranch Financial Corporation, Colorado
(39) Highlands Ranch Mortgage Company, Inc., Colorado
(40) Highlands Ranch Real Estate Corporation, Colorado
(41) Highlands Ranch Village, Inc., Colorado
(42) Hudson Commercial Corporation, Delaware
(43) International Tobacco Co. Inc., New York, Delaware
(44) Jacks Frozen Pizza, Inc., Wisconsin
(45) Jacob Leinenkugel Brewing Co., Inc., Wisconsin
(46) Jacobs Suchard International, Delaware
(47) Kraft Food Ingredients Corp., Delaware
(48) Kraft Food Service, Inc., Delaware
(49) Kraft Food Service Holding Corporation, Delaware
(50) Kraft General Foods Holdings Norway, Inc., Delaware
(51) Kraft General Foods, Inc., Delaware
(52) Kraft General Foods Intl. Svcs. Inc., Delaware
(53) Kraft General Foods, Manufacturing Corp., Delaware
(54) Kraft General Foods R&D, Inc., Delaware
(55) M.B.C. Holdings, Inc., Wisconsin
(56) MVC Financial Corporation, California
(57) Metropolitan Cheese Distributing Corporation, New York
(58) Miller Brands of Greater New Orleans, Inc., Louisiana
(59) Miller Brands of Oklahoma, Inc., Oklahoma
(60) Miller Brands of Omaha, Inc., Nebraska
(61) Miller Brands of the East Bay (three locations), California
(62) Miller Brands, Inc. (Oregon), Oregon
(63) Miller Brewing International, Inc., Delaware
(64) Miller Brewing Company, Wisconsin
(65) Miller Brewing 1855, Inc., Delaware
(66) Miller Brewing Mexico, Inc., Delaware
(67) Miller Brewing Overseas, Inc., Delaware
(68) Miller Distributing of Oklahoma, Inc., Oklahoma
(69) Mission Viejo Company, California
(70) Mission Viejo Realty, California
(71) Muratti Latin America Inc., Delaware
(72) National Dairy Products Corp., Delaware
(73) The New Town of Highlands Ranch, Inc., Colorado
(74) OMFC Service Company, Delaware
(75) One Channel Corporation, Delaware
(76) Oscar Mayer Foods Corporation, Delaware
(77) PMCC Investors No. 1 Corporation, Delaware
(78) PMCC Investors No. 2 Corporation, Delaware
(79) PMCC Investors No. 3 Corporation, Delaware
(80) PMCC Investors No. 4 Corporation, Delaware
(81) PMCC Leasing Corporation, Delaware
(82) Packaged Food & Beverage Co., Inc., Delaware
(83) Park Export Corporation, U.S. Virgin Islands
(84) Phenix Leasing Corporation, Delaware
(85) Phenix Management Corporation, Delaware
(86) Philip Morris Asia Incorporated, Delaware
(87) Philip Morris Capital Corporation, Delaware
(88) Philip Morris Companies Inc., Virginia
(89) Philip Morris Corporate Services Inc., Delaware
(90) Philip Morris Duty Free Inc., Delaware
(91) Philip Morris Europe S.A., Delaware
(92) Philip Morris Export Corporation, Delaware
(93) Philip Morris Incorporated, Virginia
(94) Philip Morris International Investment Corp., Delaware
(95) Philip Morris International Leasing Corp., Delaware
(96) Philip Morris Management Corp., New York
(97) Philip Morris Marketing S.A., Delaware
(98) Philip Morris International Inc., Delaware
(99) Philip Morris International Finance Corp., Delaware
(100) Philip Morris Latin America Sales Corp., Delaware
(101) Philip Morris Limited, Delaware
(102) Philip Morris Products Inc., Virginia
(103) Philip Morris Overseas Limited, Delaware
(104) Philip Morris Sales Inc., Delaware
(105) Philip Morris Services Inc., Delaware
(106) Philip Morris Taiwan Inc., Delaware
(107) Philip Morris Thailand Inc., Delaware
(108) Porta Park Corporation (50%), Delaware
(109) Professional Marketing Overseas Corp., Delaware
(110) Rye Ventures, Inc., Delaware
(111) SB Leasing Inc., Delaware
(112) Sand Creek Cattle Company, Colorado
(113) Santa Ana Beverage, Inc., California
(114) Shop-N Ride, Inc., Colorado
(115) Simsbury Properties Inc., Delaware
(116) Southern Gold Citrus Products Inc., Florida
(117) Taylor Group, Inc., Missouri
(118) The All American Gourmet Company, Delaware
(119) Tobacco International Latin America, Inc., Delaware
(120) Tombstone Pizza Corp., Delaware
(121) Vict. Th. Engwall & Co., Inc., Delaware

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9000 Filed 4–15–93; 8:45 am]

BILLING CODE 7035–01–M

[Docket No. AB–55 (Sub 264X)]

CSX Transportation, Inc.—Abandonment Exemption—In Grant and Miami Counties, IN

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from the prior approval requirements of 49 U.S.C. 10903–10904 the abandonment by CSX Transportation, Inc., of a 6.72-mile line segment, between milepost 147.07 at Amboy and milepost 153.82 at Santa Fe, in Miami County, IN, subject to standard labor protective conditions.

DATES: Provided no formal expression of intent to file an offer of financial assistance has been received, this exemption will be effective on May 16, 1993. Formal expressions of intent to file an offer [1] of financial assistance under 49 CFR 1152.27(c)(2) must be filed by April 26, 1993; petitions to stay must be filed by May 3, 1993; and petitions to reopen must be filed by May 11, 1993. Requests for a public use condition must be filed by May 6, 1993.

ADDRESSES: Send pleadings referring to Docket No. AB–55 (Sub-No. 264X) to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423
and
(2) Petitioner's representative: Charles M. Rosenberger, CSX Transportation,

[1] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

Inc., 500 Water Street, Jacksonville, FL 32203.

FOR FURTHER INFORMATION CONTACT: Richard B. Felder, (202) 927–5610 [TDD for hearing impaired: (202) 927–5721].

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: Dynamic Concepts, Inc., room 2229, Interstate Commerce Commission Building, Washington, DC 20423. Telephone: (202) 289–4357/4359. [Assistance for the hearing impaired is available through TDD services (202) 927–5271.]

Decided: April 5, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9002 Filed 4–15–93; 8:45 am]

BILLING CODE 7035–01–P

[Docket No. AB–55 (Sub-No. 462X)]

CSX Transportation, Inc.—Abandonment Exemption—In New Hanover County, NC

CSX Transportation, Inc. (CSXT) has filed a notice of exemption under 49 CFR Part 1152 Subpart F—*Exempt Abandonment* to abandon its approximately 1.5-mile rail line between milepost AF–286.4 at Wilmington, NC, and milepost AF–284.9 (the end of the line), in New Hanover County, NC.

CSXT has certified that: (1) No local traffic has moved over the line for at least 2 years; (2) there is no overhead traffic on the line; (3) no formal complaint filed by a user of rail service on the line (or by a State or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period. CSXT also has certified that the requirement at 49 CFR 1152.50(d)(1) (notice to government agencies) has been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on May 16, 1993, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and trail use/rail banking requests under 49 CFR 1152.29[3] must be filed by April 26, 1993. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by May 6, 1993, with: Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any pleading filed with the Commission should be sent to applicant's representative: Charles M. Rosenberger, 500 Water Street J150, Jacksonville, FL 32202.

If the notice of exemption contains false or misleading information, the use of the exemption is void *ab initio.*

Applicant has filed an environmental report which addresses the abandonment's effects, if any, on the environmental and historic resources. The Section of Energy and Environment (SEE) will issue an environmental assessment (EA) by April 21, 1993. Interested persons may obtain a copy of the EA by writing to SEE (Room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEE, at (202) 927–6248. Comments on environmental and historic preservation matters must be filed within 15 days after the EA is available to the public.

Environmental, historic preservation, public use, or trail use/banking conditions will be imposed, where appropriate, in a subsequent decision.

Decided: April 5, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–8998 Filed 4–15–93; 8:45 am]

BILLING CODE 7035–01–M

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[1] A stay will be issued routinely by the Commission in those proceedings where an informed decision on environmental issues (whether raised by a party or by the Commission's Section of Energy and Environment in its independent investigation) cannot be made before the effective date of the notice of exemption. See Exemption of Out-of-Service Rail Lines, 5 I.C.C.2d 377 (1989). Any entity seeking a stay involving environmental concerns is encouraged to file its request as soon as possible in order to permit this Commission to review and act on the request before the effective date of this exemption.

[2] See Exempt. of Rail Abandonment—Offers of Finan. Assist., 4 I.C.C.2d 164 (1987).

[3] The Commission will accept a late-filed trail use request as long as it retains jurisdiction to do so.

[Finance Docket No. 32231 (Sub. 1)]

Kokomo Rail Co., Inc. and Central Railroad Company of Indianapolis—Acquisition and Operation Exemption—Line of CSX Transportation, Inc., Between Marion and Amboy, IN

Kokomo Rail Co., Inc., and Central Railroad Company of Indianapolis have petitioned for exemptions under 49 U.S.C. 10505 from the prior approval requirements of 49 U.S.C 11343, *et seq.*, to acquire and operate, respectively, a 12.55-mile rail line from CSX Transportation, Inc., between milepost 134.48 at Marion, IN, and milepost 147.07 at Amboy, IN. Because we find that these transactions are exempt under 49 CFR 1150.31(a)(1), this notice of exemption is being published instead and the exemption petitions are dismissed.[1]

Any comments must be filed with the Commission and served on: Thomas F. McFarland, Jr., 20 North Wacker Drive, Suite 3118, Chicago, IL 60606-3101.

This notice is filed under 49 CFR 1150.31. If the notice contains false or misleading information, the exemption is void *ab initio.* Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the transaction.

Decided: April 5, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–9001 Filed 4–15–93; 8:45 am]

BILLING CODE 7035–01–P

[Docket No. AB–12 (Sub-No. 160X)]

Southern Pacific Transportation Co.—Discontinuance of Trackage Rights Exemption—In Solano County, CA

Southern Pacific Transportation Company (SPT) has filed a notice of exemption under 49 CFR 1152 Subpart F—*Exempt Abandonments and Discontinuances* to discontinue trackage rights on a 22.21-mile section of line owned by the Union Pacific Railroad Company (UP) and located in Solano County, CA. The line extends between milepost 7.86, at or near rail station Cannon, and milepost 0.00, at or near rail station Dozier, and between milepost 64.33, at or near rail station

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[1] See Finance Docket No. 32231, *et al.*, served simultaneously with this notice.

Dozier,[1] and milepost 49.98, at or near rail station Montezuma. The same line segment is the subject of an abandonment exemption proceeding at the Commission.[2]

SPT is this proceeding and UP in Docket No. AB–33 (Sub-No. 77X) have certified that: (1) No local traffic has moved over the line for at least 2 years; (2) no overhead traffic has moved over the line; (3) no formal complaint filed by a user of rail service on the line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Commission or with any U.S. District Court or has been decided in favor of the complainant within the 2-year period; and (4) the requirements at 49 CFR 1152.12 (newspaper publication) and 1152.50(d)(1) (notice to governmental agencies) have been met.[3]

As a condition to this exemption, any employee adversely affected by the discontinuance shall be protected under Oregon Short Line R. Co.—Abandonment—Goshen, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10505(d) must be filed.

This exemption will be effective on May 16, 1993, unless stayed pending reconsideration. Petitions to stay must be filed by April 26, 1993. Petitions to reopen must be filed by May 6, 1993, with: Office of Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423.

A copy of any petition filed with the Commission should be sent to applicant's representative: Gary A. Laakso, Southern Pacific Building, One Market Plaza, Room 846, San Francisco, California 94105.

If the notice of exemption contains false or misleading information, the use of the exemption is void *ab initio*.

Interested persons may obtain a copy of the EA issued in UP's abandonment proceeding in Docket No. AB–33 (Sub-No. 77X) by writing to SEE (Room 3219, Interstate Commerce Commission, Washington, DC 20423) or by calling Elaine Kaiser, Chief of SEE, at (202) 927–6248.

Decided: April 12, 1993.

By the Commission, David M. Konschnik, Director, Office of Proceedings.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93–8999 Filed 4–15–93; 8:45 am]

BILLING CODE 7035–01–M

[1] Rail station Dozier is the junction point between two portions of the line with the resultant milepost equation 0.0=64.33.

[2] On November 25, 1992, UP filed a notice of exemption under 49 CFR 1152 Subpart F in Docket No. AB–33 (Sub-No. 77X), *Union Pacific Railroad Company—Abandonment Exemption—In Solano County, CA*, to abandon the line over which SPT has trackage rights. By decision served on February 16, 1993, the Commission delayed the processing of UP's notice of exemption pending SPT's filing of a request to discontinue trackage rights.

[3] According to SPT, because it did not file an Environmental or an Historic Report, it did not give the notice of those reports required under 49 CFR 1105.7 and 1105.8. Rather, SPT incorporated the Environmental Report submitted by UP in Docket No. AB–33 (Sub-No. 77X) and the subsequent Environmental Assessment (EA) issued by the Commission's Section of Energy and Environment (SEE) on December 18, 1992. SEE has determined that, under the circumstances, SPT's incorporation of the earlier environmental documents is appropriate. SPT also incorporated UP's Historical Report by reference. Under 49 CFR 1105.6(a), however, actions that will not result in the lease, transfer, or sale of a railroad's line, sites, or structures are exempt from the historic reporting requirements.

DEPARTMENT OF JUSTICE

Immigration and Naturalization Service

[INS No. 1389–93]

Immigration and Naturalization Service User Fee Advisory Committee; Meeting

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice of meeting.

Committee holding meeting: Immigration and Naturalization Service User Fee Advisory Committee.

Date and time: May 17, 1993, at 9 a.m.

Place: The J.W. Marriott Hotel, 5150 Westheimer Road, Houston, Texas 77056, telephone number: (713) 961–1500.

Status: Open. Ninth meeting of this Advisory Committee.

Purpose: Performance of advisory responsibilities to the Commissioner of the Immigration and Naturalization Service pursuant to section 286(k) of the Immigration and Nationality Act, as amended, 8 U.S.C. 1356(k) and the Federal Advisory Committee Act, 5 U.S.C. app. 2. The responsibilities of this standing Advisory Committee are to advise the Commissioner of the Immigration and Naturalization Service on issues related to the performance of airport and seaport immigration inspectional services. This advice should include, but need not be limited to, the time period during which such services should be performed, the proper number and deployment of inspection officers, the level of fees, and the appropriateness of any proposed fee. These responsibilities are related to the assessment of an immigration user fee pursuant to section 286(d) of the Immigration and Nationality Act, as amended, 8 U.S.C. 1356(d). The Committee focuses attention on those areas of most concern and benefit to the travel industry, the traveling public, and the Federal government.

Agenda

1. Introduction of the Committee members.
2. Discussion of administrative issues.
3. Discussion of activities since last meeting.
4. Discussion of specific concerns and questions of Committee members.
5. Discussion of future traffic trends.
6. Discussion of relevant written statements submitted in advance by members of the public.
7. Scheduling of next meeting.

Public participation: The meeting is open to the public, but advance notice of attendance is requested to ensure adequate seating. Persons planning to attend should notify the contact person at least two (2) days prior to the meeting. Members of the public may submit written statements at any time before or after the meeting to the contact person for consideration by this Advisory Committee. Only written statements received at least five (5) days prior to the meeting by the contact person will be considered for discussion at the meeting.

Contact person: Elaine Schaming, Office of the Assistant Commissioner, Inspections, Immigration and Naturalization Service, room 7223, 425 I Street, NW., Washington, DC 20536, telephone number (202) 514–9587 or fax number 202–514–8345.

Dated: April 9, 1993.

Chris Sale,

Acting Commissioner, Immigration and Naturalization Service.

[FR Doc. 93–8892 Filed 4–15–93; 8:45 am]

BILLING CODE 4410–10–M

DEPARTMENT OF LABOR

Employment Standards Administration, Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1991, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, appendix, as well as such additional statutes as may from time to time be

enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersede as decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon and Related Acts," shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled "General Wage Determinations Issued Under the Davis-Bacon and Related Acts" being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

Georgia
GA93–3 (Feb. 19, 1993)
GA93–22 (Feb. 19, 1993)
Massachusetts
MA93–2 (Feb. 19, 1993)
New York
NY93–8 (Feb. 19, 1993)
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General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled "General Wage Determinations Issued Under The Davis-Bacon And Related Acts". This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country. Subscriptions may be purchased from: Superintendent of Documents, Government Printing Office, Washington, DC 20402, (202) 783–3238.

When ordering subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the three separate volumes, arranged by State. Subscriptions include an annual edition (issued on or about January 1) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC, this 9th Day of April 1993.

Alan L. Moss,

Director, Division of Wage Determinations.

[FR Doc. 93–8775 Filed 4–15–93; 8:45 am]

BILLING CODE 4510–27–M

Bureau of Labor Statistics

Labor Research Advisory Council; Meetings and Agenda

The Spring meetings of committees of the Labor Research Advisory Council will be held on May 4, 12 and 13. All of the meetings will be held in the Conference Center of the Postal Square Building, 2 Massachusetts Avenue, NE., Washington, DC.

The Labor Research Advisory Council and its committees advise the Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs. Membership consists of union research directors and staff

members. The schedule and agenda of the meetings are as follows:

Tuesday, May 4, 1993

10 a.m.–1 p.m.—Committee on Occupational Safety and Health Statistics—room 2, PSB

1. Status report on Redesign of Annual survey of Occupational Injuries and Illnesses (ROSH)
2. Proposed format for presenting data from ROSH
3. University of Michigan study on injury severity
4. BLS research on methods for measuring costs of injuries and illnesses
5. Status report on the Census of Fatal Occupational Injuries
6. "Capture/Recapture" method for estimating undercounts of fatal injuries
7. Program budgets
8. Other business

Wednesday, May 12, 1993

9:30 a.m.—Committee on Employment and Unemployment Statistics—rooms 1 and 2, PSB

1. Discussion: Structural, Cyclical and Frictional Unemployment: Concepts, Potential Definitions, and Evidence
2. Reports
a. Status of Employment and Unemployment Statistics budget
b. Mass layoff statistics
c. BLS survey of training in industry
d. Immigration legislation and measurement of labor shortages
e. Measuring the impact of defense cutbacks
f. Issues in measuring the "contingent" workforce

1 p.m.—Committee on Productivity, Technology and Growth Committee on Foreign Labor Statistics—rooms 1 and 2, PSB

1. Summary of recent developments in the Office of Productivity and Technology
2. Service sector productivity
a. An overview: problems of developing improved service sector measures
b. Service sector work at the industry level
3. Report on international technical assistance and training
4. Study of the impact of defense expenditures on unemployment

Thursday, May 13, 1993

9:30 a.m.—Committee on Wages and Industrial Relations—room 2, PSB

1. Review of work in progress
2. Employment cost index public use file
3. New PC system to 'cost out' collective bargaining settlements
4. Impact of the Financial Accounting Standards Board's Standard 106 (unfunded liability for health insurance for future retirees) on the Employment Cost Index

1:30 p.m.—Committee on Prices and Living Conditions—rooms 1 and 2, PSB

1. Producer Price Index
a. New indexes for hospitals
2. Consumer Price Index
a. Mail order sales
b. Coupons
3. International Prices
a. Revision status
4. Other business

The meetings are open to the public. Persons planning to attend these meetings as observers may want to contact Wilhelmina Abner on (Area Code 202) 606–6608.

Signed at Washington, DC, this 9th day of April 1993.

William G. Barron, Jr.,

Deputy Commissioner.

[FR Doc. 93–8974 Filed 4–15–93; 8:45 am]

BILLING CODE 4510-24-M

Employment and Training Administration

[TA–W–28,078]

Beaver Dam Products, Beaver Dam, WI; Affirmative Determination Regarding Application for Reconsideration

On March 26, 1993, Local #793 of the Allied Industrial Workers of America (AIW) requested administrative reconsideration of the Department of Labor's Notice of Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers at the subject firm. The Department's Negative Determination was issued on March 1, 1993 and published in the **Federal Register** on March 22, 1993, (58 FR 15383).

The union states that Canadian components on the New Yorker and 5th Avenue have replaced those of Beaver Dam's.

Conclusion

After careful review of the application, I conclude that the claim is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, DC, this 7th day of April 1993.

Robert O. Deslongchamps,

Director, Office of Legislation & Actuarial Services Unemployment Insurance Service.

[FR Doc. 93–8971 Filed 4–15–93; 8:45 am]

BILLING CODE 4510-30-M

[TA–W–28,284]

GLG Energy, L.P., Austin, TX, et al.; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In the Matter of: GLG Energy, L.P., Austin, TX and Operating at Various Locations in the Following States: TA–W–28,284A TX (except Austin), TA–W–28,284B CO, TA–W–28,284C WY.

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on March 5, 1993, applicable to all workers of GLG Energy, L.P., Austin, Texas. The notice was published in the **Federal Register** on March 22, 1993 (58 FR 15384).

At the request of the State Agency, the Department is amending the certification to include worker separations in other locations in Texas and also at various locations in Colorado and Wyoming.

The amended notice applicable to TA–W–28,284 is hereby issued as follows:

"All workers of GLG Energy, L.P., Austin, Texas and operating at other locations in Texas (except Austin) (TA–W–28,284A) and in the States of Colorado (TA–W–28,284B) and Wyoming (TA–W–28,284C) who became totally or partially separated from employment on or after January 21, 1992 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974."

Signed in Washington, DC, this April 7, 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93–8970 Filed 4–15–93; 8:45 am]

BILLING CODE 4510-30-M

[TA–W–27,847; TA–W–27,847A; TA–W–27,847B]

South Texas Drilling and Exploration, Inc., San Antonio, TX, Employer Select Management, TX, and Administrative Resources, Inc., TX; Amended Certification Regarding Eligibility To Apply for Worker Adjustment Assistance

In accordance with section 223 of the Trade Act of 1974 (19 U.S.C. 2273) the

Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on January 26, 1993, applicable to all workers of South Texas Drilling and Exploration, Inc., of San Antonio, Texas. The notice was published in the **Federal Register** on February 11, 1993 (58 FR 8063).

At the request of the State Agency, the Department is amending the certification to include leased employees at South Texas Drilling and Exploration who were separated as a result of the adverse impact of imported crude oil and natural gas.

The amended notice applicable to TA–W–27,847 is hereby issued as follows:

"All workers of South Texas Drilling and Exploration, Inc., San Antonio, Texas who became totally or partially separated from employment on or after September 3, 1991 including leased employees of Employer Select Management and Administrative Resources, Inc., who were employed exclusively at South Texas Drilling and Exploration, Inc., who were separated as a result of the impact of imported crude oil and natural gas on or after September 3, 1991 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974."

Signed in Washington, DC, this 7th day of April 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 93–8973 Filed 4–15–93; 8:45 am]

BILLING CODE 4510–30–M

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the Appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than April 26, 1993.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than April 26, 1993.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210.

Signed at Washington, DC, this 5th day of April 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner (Union/workers/firm)	Location	Date received	Date of petition	Petition No.	Articles produced
Tuckes Drilling Co., Inc (Workers)	San Angelo, TX	04/05/93	03/18/93	28,503	Drilling (Oil and Gas)
Ranken Energy Corp (Workers)	Edmond, OK	04/05/93	03/15/93	28,504	Oil and Gas.
OSRAM Sylvania Inc-Circuit Assembly (Workers).	Williamsport, PA	04/05/93	03/21/93	28,505	Computer components.
Nevada Equipment Wholesalers (Workers).	Las Vegas, NV	04/05/93	03/18/93	28,506	Drill press and heavy equipment.
Holden Manufacturing Co (ILGWU)	Holden, MO	04/05/93	03/23/93	28,507	Women's sportswear.
Glacier Vandervell, Inc (Workers)	Bellefontaine, OH	04/05/93	02/09/93	28,508	Fluid film bearings.
General Electric Co (Workers)	Syracuse, NY	04/05/93	03/17/93	28,509	Mine-hunting sonar for royal navy.
Alyeska Pipeline Service (Co)	Anchorage, AK	04/05/93	03/22/93	28,510	Delivery services in oil industry.
Sure Fit (Co)	Bethlehem, PA	04/05/93	03/26/93	28,511	Household furnishings.
Sure Fit (Co)	El Paso, TX	04/05/93	03/26/93	28,512	Household furnishings.
Swift Adhesives (Workers)	Portland, OR	04/05/93	03/17/93	28,513	Adhesives.
Simon Petroleum Technology Corp (Workers).	Houston, TX	04/05/93	03/23/93	28,514	Seismic operations.
Logic Sciences, Inc (Co)	Houston, TX	04/05/93	03/26/93	28,515	Computer interpreting device.
C.A. Reed, Inc. (Workers)	Williamsport, PA	04/05/93	03/24/93	28,516	Paper party ware.
Tex-Style, Inc (AIW)	Cincinnati, OH	04/05/93	03/23/93	28,517	Home furnishing.
Joey Mfg, Inc (ILGWU)	Pittston, PA	04/05/93	03/29/93	28,518	Ladies' evening dresses.
CRM Services (Workers)	Crane, TX	04/05/93	03/22/93	28,519	Clerical services.
Granada Industries Corp (Workers)	Martinsburg, WV	04/05/93	03/25/93	28,520	Ladies' blouses, dresses, robes, etc.
Digital Equipment Corp (Workers)	Houston, TX	04/05/93	03/08/93	28,521	Sales and service computers.
Jane & Linda Sportswear (ILGWU)	Lebanon, KY	04/05/93	03/24/93	28,522	Ladies skirts and shorts.
Conemaugh & Black Lick Railroad (USWA).	Johnstown, PA	04/05/93	03/19/93	28,523	Provides transportation of bar products.
BRK Electronics, Inc (Co)	Aurora, IL	04/05/93	03/24/93	28,524	Smoke detectors, rechargeable flashlight.
Bethlehem Steel Corp (USWA)	Johnstown, PA	04/05/93	03/19/93	28,525	Bar, rod and wire.
Belcraft Skirts (Workers)	Redgewood, NY	04/05/93	03/26/93	28,526	Skirts and pants.
Armco, Inc (USWA)	Heidelberg, PA	04/05/93	03/19/93	28,527	Steel roof, floor and bridge deck.
HILTI Steel Industry/SISCO Inc (USWA).	Tulsa, OK	04/05/93	03/20/93	28,528	Steel molds and stools.

APPENDIX—Continued

Petitioner (Union/workers/firm)	Location	Date received	Date of petition	Petition No.	Articles produced
Neenah Foundry Co (GMP)	Neenah, WI	04/05/93	03/01/93	28,529	Iron castings.
LeDamor (Workers)	Feasterville, PA	04/05/93	03/24/93	28,530	Women's sportswear.

[FR Doc. 93–8967 Filed 4–15–93; 8:45 am]
BILLING CODE 4510-30-M

[TA–W–27,863 Ashland, OH; TA–W–27,864 Shelby, OH]

U-Brand Corp.; Negative Determination Regarding Application for Reconsideration

By an application dated March 8, 1993, the parent company requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on February 12, 1993 and was published in the **Federal Register** on March 11, 1993 (58 FR 13506).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justified reconsideration of the decision.

Company officials claim that the Department's survey of customers is faulty since it did not include indirect imports.

The workers at Ashland produced malleable iron pipe fittings. The Shelby facility performed warehousing and shipping functions.

The Department's denial was based on the fact that the "contributed importantly" test of the increased import criterion was not met. The "contributed importantly" test is generally demonstrated through a survey of the workers' firm's customers. The Department's survey of the subject firms' major customers shows that none imported foreign pipe fittings. The survey included indirect imports—purchases from domestic firms who import.

Investigation findings also show that the dominant cause for the worker separations at Ashland and Shelby was the sale of U-Brand Corporation to its competitor who closed down Ashland.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this 8th day of April 1992.

Robert O. Deslongchamps,

Director, Office of Legislation & Actuarial Service, Unemployment Insurance Service.

[FR Doc. 93–8968 Filed 4–15–93; 8:45 am]
BILLING CODE 4510-30-M

NUCLEAR REGULATORY COMMISSION

Documents Containing Reporting or Recordkeeping Requirements; Office of Management and Budget Review

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of the OMB Review of Information Collection.

SUMMARY: The Nuclear Regulatory Commission (NRC) has recently submitted to OMB for review the following final rule amendments for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

1. Type of submission, new, revised, or extension: Revision.

2. The title of the information collection: 10 CFR parts 30, 40, 70, and 72; Decommissioning Recordkeeping and License Termination: Documentation Additions.

3. The form number if applicable: Not applicable.

4. How often is the collection required: Initial update of the decommissioning listing with updates at least once every 2 years until termination of license. For those licensees requiring approval of a decommissioning plan, one-time submittal of this list of areas and a list of decontaminated equipment to be left onsite at license termination.

5. Who will be required or asked to report: 10 CFR parts 30, 40, 70 and 72 NRC licensees and Agreement State licensees except those who possess only non-leaking sealed sources, or byproduct material with a half-life of less than 65 days, or depleted uranium used only for shielding or as penetrators in unused munitions.

6. An estimate of the number of respondents: Approximately 3,309 of the approximately 23,500 NRC and Agreement State licensees will maintain the decommissioning listing documentation. An average of 19 licensees annually will submit the list as part of their decommissioning plan. An average of 22 licensees annually will submit the equipment list at license termination.

7. An estimate of the number of hours annually needed to complete the requirement or request: 3,353 hours (1 hour per licensee), 44 for reporting (submittal of the decommissioning list and equipment list) and 3,309 for recordkeeping.

8. An indication of whether Section 3504(h), Public Law 96–511 applies: Applicable.

9. Abstract: The final rule would require materials licensees (exempting those who possess sealed sources or byproduct material having less than a 65-day half-life) to maintain a list identifying all restricted areas where licensed materials and equipment are or have been used or stored, all areas where documentation is required in the current decommissioning rule for unusual occurrences or spills, and all areas outside of restricted areas where waste has been buried or containing material such that if the license were terminated, the licensee would be required to decontaminate the area or seek special approval for disposal. The final rule also requires licensees that require a decommissioning plan to submit the above specified list as well as a list of specific information (after completion of decommissioning) on certain decontaminated equipment that will remain onsite at the time of license termination.

Copies of the submittal may be inspected or obtained for a fee from the NRC Public Document Room, 2120 L Street, NW, (Lower Level), Washington DC.

Comments and questions can be directed by mail to the OMB reviewer: Ronald Minsk, Office of Information and Regulatory Affairs, (3150–0017, 3150–

0020, 3150–0009, 3150–0132), NEOB–3019, Office of Management and Budget, Washington, DC 20503.

Comments may also be communicated by telephone at (202) 395–3084. The NRC Clearance Officer is Brenda Jo Shelton, (301) 492–8132.

Dated at Bethesda, Maryland, this 6th day of April, 1993

For the Nuclear Regulatory Commission.

Gerald F. Cranford,

Designated Senior Official for Information Resources Management.

[FR Doc. 93–8934 Filed 4–15–93; 8:45 am]

BILLING CODE 7590–01–M

OFFICE OF MANAGEMENT AND BUDGET

Office of Federal Procurement Policy

SMALL BUSINESS ADMINISTRATION

Interim Policy Directive, Small Business Competitiveness Demonstration Program

AGENCY: Office of Federal Procurement Policy (OFPP); Small Business Administration (SBA).

ACTION: Interim policy directive with request for comments.

SUMMARY: The OFPP and SBA are amending the final policy directive and test plan, dated August 31, 1989, which implement the Small Business Competitiveness Demonstration Program Act of 1988, title VII, Public Law 100–656. Section 201 of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Pub. L. 102–366) extends the Small Business Competitiveness Demonstration Program through September 30, 1996; section 202 contains several other amendments to the Program. These amendments are being implemented in this interim policy directive.

EFFECTIVE DATE: April 16, 1993.

COMMENT DATE: Comments on the interim policy directive should be submitted to the Addresses shown below on or before June 15, 1993, to be considered for formulation of the final policy directive.

ADDRESSES: Comments on the policy directive should be submitted to: Allan V. Burman, Administrator, Office of Federal Procurement Policy, 725 17th Street, NW., room 9001, Washington, DC 20503.

Comments on the information collection requirements contained in Attachment A of the policy directive should be submitted both to the OFPP Administrator at the above address and to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503—Attention: Desk Officer for the Federal Acquisition Regulation.

FOR FURTHER INFORMATION CONTACT: Karen Maris, Deputy Associate Administrator, (202) 395–4955; or Robert Neal, Deputy Associate Administrator, (202) 395–6168.

SUPPLEMENTARY INFORMATION:

A. Background

The Small Business Competitiveness Demonstration Program was established to test the effectiveness of eliminating small business set-asides in certain industries. The program has two primary objectives: (1) To demonstrate whether small businesses in certain industry groups can compete successfully on an unrestricted basis for Federal contracts, and (2) to demonstrate whether targeted goaling and management techniques can expand Federal contract opportunities for small businesses in industry categories where such opportunities historically have been low despite adequate numbers of small business contractors in the economy.

Section 201 of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (the Act) extends the Program, which was originally scheduled to expire on December 31, 1992, through September 30, 1996. The Act also makes several other amendments to the Program which are being implemented in this interim policy directive.

Section 202(b)(1) requires that when a participating agency misses its small business participation goal, restricted competition shall be reinstituted only at those buying activities that failed to attain the goal. Section 202(g) limits coverage of architectural and engineering (A&E) services to contracts awarded under the qualification-based procedures required by 40 U.S.C. 541 *et seq.* (the "Brooks A–E Act"). Section 202(h) reduces the small business participation goal for A&E services from 40 percent to 35 percent until OFPP implements certain data collection improvements required by the Act, including the limitation of A&E coverage to contracts awarded under the Brooks A–E Act.

OFPP also is required to develop and implement a simplified system to collect data on the participation of small business concerns, including small disadvantaged business concerns, as other than prime contractors. This system will apply only to the Environmental Protection Agency, the National Aeronautics and Space Administration, the Army Corps of Engineers (Civil Works), and the Department of Energy. A separate proposed rule to implement this requirement is being issued by OFPP.

Other changes being made to the policy directive and test plan include the following. Language has been added to more specifically provide that the 40 percent small business goal for construction applies individually to each of the major groups that comprise the industry. Participating agencies are instructed that any combination of Federal Procurement Data System and Standard Industrial Classification codes for A&E Services may be counted toward their small business goal. A requirement for public notice in the **Federal Register**, when participating agencies reinstitute restricted or full and open competition, has been added. The reporting format (Attachment B to the test plan) has been modified to require dollars to be reported in thousands and percentages to be stated in whole numbers.

B. Regulatory Flexibility Act and Executive Order 12291

The Program may have a significant economic impact on a substantial number of small businesses, within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, and a Regulatory Flexibility Analysis is necessary. In addition, for the purposes of E.O. 12291, OFPP and SBA have determined that this interim policy directive is a major rule because it will have an annual effect on the economy of $100 million or more.

However, since this is a test program, which has been extended by statute through September 30, 1996, an evaluation of the consequences of the test program at this time would be inappropriate and premature. The economic impact of this test program will be determined at its conclusion.

C. Paperwork Reduction Act

The information collection requirements contained in the policy directive and test plan were previously approved by OMB and assigned OMB control number 9000–0100. Public Law 101–37, however, expanded the universe of contracts requiring this data submission. A revised information collection request has been submitted to OMB for approval under the Paperwork Reduction Act (44 U.S.C. 35).

Dated: April 8, 1993.

David Baker,

Associate Administrator, Office of Federal Procurement Policy.

Robert J. Moffitt,

Associate Administrator for Procurement Assistance, Small Business Administration.

April 8, 1993.

Memorandum for:

The Secretary of Agriculture
The Secretary of Defense
The Secretary of Energy
The Secretary of Health and Human Services
The Secretary of the Interior
The Secretary of Transportation
The Administrator of the Environmental Protection Agency
The Administrator of General Services
The Administrator of the National Aeronautics and Space Administration
The Secretary of Veterans Affairs

Subject: The Small Business Competitiveness Demonstration Program

1. *Purpose.* This memorandum provides policy direction to the participating agencies for implementation of the Small Business Competitiveness Demonstration Program Act of 1988 (title VII, Public Law 100–656), as amended by sections 23–27 of the Business Opportunity Development Reform Act Technical Corrections Act (Public Law 101–37), and sections 201 and 202 of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Public Law 102–366).

2. *Authority.* This memorandum is issued pursuant to section 715 of Public Law 100–656, which requires that the Office of Federal Procurement Policy (OFPP) and the Small Business Administration (SBA) issue a policy directive to ensure consistent government-wide implementation of title VII in the Federal Acquisition Regulation (FAR); section 202(i) of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Public Law 102–366), which requires appropriate modifications to the policy directive to conform to amendments made by that Act, and section 15 of the Office of Federal Procurement Policy Act, 41 U.S.C. 413, which provides for the testing of innovative procurement methods and procedures.

3. *Background.* Section 15(a) of the Small Business Act mandates that small businesses receive a fair proportion of Federal procurements. To achieve this goal, subpart 19.5 of the FAR requires that Federal agencies reserve, or set aside, procurements for exclusive small business participation when a contracting officer determines that two or more small businesses are capable of providing the goods or services at reasonable prices. While restricting procurements for exclusive small business participation has been very effective in assuring a small business share of Federal contracts, one unintended result is a concentration of awards in certain industries often dominated by small businesses. A further result is that agencies expend resources in those industries that are conducive to high levels of small business participation rather than expand the base of small business contracting into areas where small businesses do not traditionally obtain a significant share of procurement awards.

4. *Policy.* The Small Business Competitiveness Demonstration Program is designed to provide for enhanced goals for small businesses in certain industry groups and to expand small business participation in a broader range of industry categories. The Program is conducted under the authority of section 15 of the Office of Federal Procurement Policy Act which provides for the test of unique and innovative procurement procedures and techniques. The goal of the Program is to test the ability of small businesses in certain designated industry groups to retain a fair proportion of procurement awards in unrestricted competition in those industry groups. The Act designates SBA to act as the executive agent for OFPP in conducting the test. The procedures for implementing the test required by the Program are set forth in the attached test plan.

5. *Implementation.* This policy directive shall be implemented in FAR part 19. Pursuant to section 714(a) of Public Law 100–656, provisions of the FAR that are inconsistent with this policy directive and the attached test plan are hereby waived.

6. *Expiration Date.* The Small Business Competitiveness Demonstration Program and this policy will expire on September 30, 1996.

David Baker for Allan V. Burman,

Administrator, Office of Federal Procurement Policy.

Robert J. Moffitt,

Associate Administrator for Procurement Assistance, Small Business Administration.

Small Business Competitiveness Demonstration Program Test Plan

I. Purpose

This document implements the Small Business Competitiveness Demonstration Program Act of 1988 (title VII, Public Law 100–656), as amended by sections 23–27 of the Business Opportunity Development Reform Act Technical Corrections Act (Public Law 101–37), and sections 201 and 202 of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Public Law 102–366). There are three primary purposes for this Program. First, the Program seeks to demonstrate whether the competitive capabilities of small business firms in certain industry groups will enable them to successfully compete on an unrestricted basis for Federal contracts. Second, the Program attempts to demonstrate whether the use of targeted goaling and management techniques by procuring agencies, in conjunction with the Small Business Administration (SBA), will expand small business participation in Federal contracting opportunities that have been historically low despite adequate numbers of qualified small business contractors in the economy. Finally, the Program seeks to demonstrate whether expanded use of full and open competition adversely affects small business participation in certain industry groups, taking into consideration the numerical dominance of small firms, the size and scope of most contracting opportunities, and the competitive capabilities of small firms.

II. Authority

The Program is established pursuant to the Small Business Competitiveness Demonstration Program Act of 1988 (title VII, Public Law 100–656), sections 201 and 202 of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Public Law 102–366), and section 15 of the Office of Federal Procurement Policy Act, 41 U.S.C. 413.

III. Program Requirements

A. Applicability

1. The Program shall cover the period from January 1, 1989, through September 30, 1996. The Program will consist of two major components: (1) Four Designated Industry Groups, which test unrestricted competition, and (2) ten Targeted Industry Categories, which test enhanced small business participation. Contracts resulting from solicitations issued from January 1, 1989 through September 30, 1996, and any subsequent modifications to such contracts, are covered by this Program

2. Contract awards in the following designated industry groups are covered by this Program:

a. Construction under standard industrial classification (SIC) codes that comprise major groups 15, 16, and 17 (excluding dredging—Federal

Procurement Data System (FPDS) service codes Y216 and Z216);

b. Refuse systems and related services, including portable sanitation services, under SIC code 4212 or 4953, limited to FPDS service code S205;

c. Architectural and engineering (A&E) services (including surveying and mapping) under SIC codes 7389, 8711, 8712, or 8713 (limited to FPDS service codes C111 through C216, C219, T002, T004, T008, T009, T014, and R404), awarded under the qualification-based selection procedures required by 40 U.S.C. 541 *et seq.* (the "Brooks A–E Act"); and

d. Non-Nuclear ship repair—ship repair (including overhauls and conversions) performed on non-nuclear propelled and nonpropelled ships under SIC code 3731, limited to FPDS service codes J998 (repair performed east of the 108th meridian) and J999 (repair performed west of the 108th meridian).

3. Targeted industry categories for enhanced participation will be determined by each participating agency, in conjunction with SBA.

4. Contract awards under the Federal Schedule Program are not covered by the Program.

B. Participating Agencies.

The following agencies are participants in the Program:

1. The Department of Agriculture,
2. The Department of Defense, except the Defense Mapping Agency,
3. The Department of Energy,
4. The Department of Health and Human Services,
5. The Department of Transportation,
6. The Environmental Protection Agency,
7. The General Services Administration,
8. The National Aeronautics and Space Administration,
9. The Department of Veterans Affairs, and
10. The Department of the Interior

C. Agency Goals for the Four Designated Industry Groups

1. Each participating agency shall have a small business participation goal that is 40 percent of the agency's total contract dollars awarded for construction major group 15, major group 16 and major group 17; refuse systems and related services, and non-nuclear ship repair. For A&E services, however, each agency shall have a small business participation goal of 35 percent until the system for collecting data regarding other than prime contract awards (as required by section 202(d) of Public Law 102–366) has been implemented. In addition, each participating agency must make a good faith effort to assure that emerging small businesses receive not less than 15 percent of the agency's total contract dollars awarded for each of the four designated industry groups.

2. The Small Business Competitiveness Demonstration Program Act of 1988 defines an emerging small business as one whose size is no greater than 50 percent of the numerical size standard applicable to the SIC Code assigned to the procurement. Subject to the requirements of paragraph III.D.3 below, contract opportunities in the four designated industry groups, which have an estimated award value equal to or less than the reserve amount established for emerging small businesses, are reserved for such businesses.

3. Contract awards made to fulfill the 15 percent goal for emerging small businesses also count toward attainment of the 40 percent and 35 percent goals. All prime contract awards to small businesses, including awards under section 8(a) of the Small Business Act, section 1207 of the FY 87 National Defense Authorization Act, and sole source awards, count toward attainment of goals.

D. Procurement Procedures for the Four Designated Industry Groups

Participating agencies shall use the following procedures for procurements in the four designated industry groups.

1. Full and Open Competition for Contracts in Excess of the Emerging Small Business Reserve Amount

a. Subject to the requirements of the Competition in Contracting Act of 1984, participating agencies are required to use full and open competition for all solicitations issued on or after January 1, 1989, in the four designated industry groups, if the anticipated award value exceeds the dollar amount reserved for emerging small businesses (unless the procurement is placed under section 8(a) of the Small Business Act or set aside under section 1207 of the FY 87 National Defense Authorization Act). Each participating agency shall continue to use full and open competition as long as quarterly reviews show that the agency's 40 percent and 35 percent goals are being attained. The continued use of full and open competition is not affected by an agency's failure to meet its 15 percent award goals for emerging small businesses.

b. Notwithstanding the provisions of paragraph III.D.1.a., above, the Department of Defense shall solicit contracting opportunities for A&E services (including surveying and mapping) in accordance with the requirements of subsections (a) and (b) of section 2855 of title 10, United States Code.

2. Restricted Competition for Contracts in Excess of the Emerging Small Business Reserve Amount

a. If any participating agency's quarterly review of its awards to small businesses in the four designated industry groups shows that the agency has failed to attain its 40 or 35 percent goals for any of the groups, subsequent contracting opportunities, in excess of the amount reserved for emerging small businesses, shall be solicited through competition restricted to eligible small businesses only at the organizational unit(s) within the agency that failed to attain the small business participation goals. (Organizational unit(s) shall be no larger than the major agency components or services, e.g., Army, Air Force, Navy, etc. for Department of Defense, regional offices for the General Services Administration, or space flight and research centers for the National Aeronautics and Space Administration.) Such solicitations (unless placed under section 8(a) of the Small Business Act or set aside under section 1207 of the FY 87 National Defense Authorization Act) shall be conducted in accordance with section 15(a) of the Small Business Act and subpart 19.5 of the Federal Acquisition Regulation (FAR).

b. Agencies shall promptly return to the use of full and open competition upon determining that their contract awards to small business concerns again meet the required goals.

c. Modifications to agency solicitation practices (instituting restricted competition and reinstituting full and open competition) shall be made as soon as practicable, but no later than the beginning of the quarter following completion of the review indicating the need for such change. The reinstitution of restricted competition or full and open competition shall be announced to the public through a notice published in the **Federal Register** if restricted competition or full and open competition is to be broadly reimposed by a participating agency. "Special notices" in the Commerce Business Daily shall be used periodically to supplement such **Federal Register** notices, and may be used as an alternative means of providing such notices, if the reinstitution of restricted competition or full and open competition will affect only a limited number of buying activities.

3. Reserve Program for Emerging Small Businesses

a. The emerging small business reserve amount is $25,000, or such higher amount as OFPP sets in the event that emerging small business concerns are not receiving 15 percent of the total dollar value of contract awards in one or more of the four designated industry groups. Any required adjustments to the emerging small business reserve amount will be made semiannually by industry group.

b. Competition for all contract opportunities in the four designated industry groups with an estimated award value that is equal to or less than the merging small business reserve amount shall be restricted to emerging small businesses, provided that the contracting officer determines that there is a reasonable expectation of obtaining offers from two or more responsible emerging small businesses that will be competitive in terms of market price, quality, and delivery. If no such reasonable expectation exists, requirements will be processed in accordance with FAR subpart 13.105 or in accordance with FAR subpart 19.5 or 19.8. However, if no such reasonable expectation exists where OFPP has raised the small business reserve amount to a level over $25,000, requirements over $25,000 will be processed in accordance with paragraphs III.D.1 and III.D.2, above.

c. The use of small purchase procedures is not required under the reserve program; any competitive source selection method may be used. The reserve program applies only to new awards within the emerging small business reserve threshold. Modifications within the scope of work of contracts having an initial award value in excess of the emerging small business reserve amount are not subject to the reserve program.

d. Each solicitation under the Program that utilizes small purchase procedures shall include the applicable SIC code and size standard for the procurement. The exception for small purchases in FAR subpart 19.303(a) is hereby waived for the Program.

4. Solicitation Provisions for Procurements in the Four Designated Industry Groups

a. The provision set forth in Attachment A entitled "Small Business Concern Representation For The Small Business Competitiveness Demonstration Program (AUGUST 1989)" shall be inserted in full text in all solicitations issued by the participating agencies under the Small Business Competitiveness Demonstration Program for the four designated industry groups. Contracting officers may modify paragraph (c) of the provision to include only the applicable information (i.e., number of employees or gross receipts) based on the size standard applicable to the particular solicitation.

b. The clause set forth in Attachment A entitled "Notice of Emerging Small Business Set-Aside (DEC 1988)" shall be inserted in full text in all solicitations and resulting contracts restricted to emerging small businesses pursuant to paragraph III.D.3.

c. The face of each award issued by a participating agency under the Small Business Competitiveness Demonstration Program for the four designated industry groups shall contain a statement that the award is being issued pursuant to such Program.

E. Agency Programs for Targeted Industry Categories With Limited Small Business Participation

1. Each participating agency is required to select ten industry categories (four-digit SIC Code or some segmented portion(s) of such code(s), as identified by FPDS product or service code) as targeted categories for expansion of small business participation.

2. In order to achieve such expanded participation, agencies shall select categories that represent products and services purchased in substantial quantities by the agency; that historically have had a small business participation rate of less than 10 percent by category; and, in which there is a significant amount of small business productive capacity that has not been utilized by the Government.

3. Each participating agency shall consult with the Administrator of SBA in selecting the ten targeted categories, developing the plan for expanded small business participation, and establishing the goals for the Program. Upon completion of their consultation with SBA, participating agencies shall publish in the **Federal Register**, an announcement soliciting public comment on that agency's program for expansion of small business participation in the targeted categories.

4. Each plan shall be submitted to the Administrator of SBA and shall contain a detailed time-phased strategy with incremental goals, including reporting on goal attainment. To the extent practicable, provisions that encourage and promote teaming and joint ventures shall be included. These provisions should permit small business firms to effectively compete for contracts that individual small businesses would be ineligible to compete for because of lack of production capacity or capability. Such joint ventures or teams shall comply with the applicable small business guidelines. (See 13 CFR 121.3(a)(vii)(C) and 121.5(a)).

5. Participating agencies shall report to OFPP and SBA on the results of the expansion program regarding the ten targeted categories on the same quarterly schedule as required for the four designated industry groups.

6. Goal attainment for the ten targeted industry categories shall be determined on the basis of awards to U.S. business firms.

7. The provision set forth in Attachment A entitled "Small Business Size Representation For Targeted Industry Categories Under The Small Business Competitiveness Demonstration Program (AUGUST 1989)" shall be inserted in full text in any solicitation issued in each of the ten targeted industry categories under the Small Business Competitiveness Demonstration Program that is expected to result in a contract award in excess of $25,000. Contracting officers may modify the provision to include only the applicable information (i.e., number of employees or gross receipts) based on the size standard applicable to the particular solicitation.

8. The face of each award issued in any of the ten targeted industry categories under the Small Business Competitiveness Demonstration Program shall contain a statement that the award is being issued pursuant to such Program.

IV. Monitoring and Reporting for Four Designated Industry Groups

A. Monitoring of Goals for the Four Designated Industry Groups

1. Each participating agency shall monitor its attainment of its small business and emerging small business participation goals on a quarterly basis. Written reports must be made to OFPP and SBA as to whether goals have been attained for each industry group, as specified in paragraph IV.A.3, below. The Department of Defense shall submit a report that separately identifies performance by the Army, Air Force, Navy and the Defense Agencies. The report submitted by the General Services Administration shall separately identify performance by the Public Building Service. Reports shall be submitted within 60 days after the end of each quarter and shall specify the industry groups or codes for which restricted or full and open competition have been reimposed.

2. Agencies shall monitor their goal attainment for the first three quarters based on aggregate data for the following time periods:

a. First quarterly review: 1/1/89–3/31/89
b. Second quarterly review: 1/1/89–6/30/89
c. Third quarterly review: 1/1/89–9/30/89

Thereafter, monitoring is to be based on aggregate data for the four preceding quarters.

3. Attainment of small business and emerging small business participation goals for the four designated industry groups will be monitored by each participating agency. Monitoring of goal attainment will be based on awards (and any subsequent modifications to those awards) in the individual codes comprising the industry, as specified in paragraph IV.B., below.

4. Any necessary modifications to agency solicitation practices for the purpose of achieving the agencys small business participation goals (instituting restricted competition or reinstatement full and open competition) will be accomplished for each of the industry groups as follows:

a. Construction (excluding dredging)
   i. Major group 15
   ii. Major group 16
   iii. Major group 17
b. Refuse systems and related services.
c. A&E services (including surveying and mapping), limited to contracts awarded under the qualification-based selection procedures required by 40 U.S.C. 541 *et seq.* (the "Brooks A-E Act").
d. Non-nuclear ship repair.

However, if goal attainment for any individual FPDS service code within the A&E services or non-nuclear ship repair industry groups falls below 35 percent, the agency shall reinstitute set-asides for that individual service code, even if overall goal attainment in the industry group is 40 percent (35 percent for A&E services) or more. In addition, if goal attainment for any individual SIC code within one of the major groups comprising the construction industry group falls below 35 percent, the agency shall reinstitute set-asides for that individual SIC code, even if overall goal attainment in the major group is 40 percent or more.

5. Agencies shall monitor goal attainment in the four designated industry groups by reviewing total prime contract award dollars to (a) all U.S. business firms (b) small U.S. business concerns and (c) emerging small U.S. business concerns.

6. OFPP and SBA will closely monitor the Program using data from the FPDS to ensure that each participating agency makes a consistent effort to achieve goals evenly across all individual codes that comprise a designated industry group. Data shall be retrieved in the format set forth at Attachment B.

7. All prime contract awards to small businesses, including awards under section 8(a) of the Small Business Act, section 1207 of the FY 87 National Defense Authorization Act, and sole source awards, count toward attainment of goals.

B. Codes for Monitoring and Reporting Goal Attainment for the Four Designated Industry Groups

1. Refuse Systems and Related Services

The Small Business Competitiveness Demonstration Program Act of 1988 outlines the SICs that are included in the designated industry groups. However, in the area of refuse systems and related services, SICs 4212 and 4953 include services that should not be included in the Program. The Program is designed to test small firms' competitiveness generally in procurements for the collection, transportation, and disposal of residential and nonhazardous commercial garbage, refuse and waste materials. For example, contracts for the regular collection and disposal at publicly or privately operated landfills of residential and nonhazardous commercial solid waste, garbage, debris, or other refuse from military installations, federal office buildings, and other federal facilities, and garbage processing and recycling activities, should be included. Contracts for the operation of those facilities, collection and disposal of acid, radioactive, or other hazardous waste should not be included. Therefore, participating agencies shall use FPDS service code S205 (trash/garbage collection services—including portable sanitation services) to monitor goal attainment for refuse systems and related services.

2. Architectural and Engineering Services

a. The statute provides that A&E services (including surveying and mapping), shall include contracts assigned SICs 8711, 8712, 8713, and 7389 (if identified as mapping) and awarded under the qualification-based selection procedures required by 40 U.S.C. 541 *et seq.* (the "Brooks A-E Act"). Since SIC 7389 includes many more services than mapping, participating agencies shall use the following FPDS service codes to monitor goal attainment for mapping services:

T002 Cartography services
T004 Charting services
T008 Photogrammetry services
T009 Aerial photographic services
T014 Topography services

b. Participating agencies shall use the following FPDS service codes to monitor A&E services under SICs 8711, 8712, and 8713:

C111 Administrative and Service Buildings
C112 Airfield, Communication and Missile Facilities
C113 Educational Buildings
C114 Hospital Buildings
C115 Industrial Buildings
C116 Residential Buildings
C117 Warehouse Buildings
C118 Research and Development Facilities
C119 Other Buildings
C121 Conservation and Development
C122 Highways, Roads, Streets and Bridges
C123 Electric Power Generation (EPG)
C124 Utilities
C129 Other Non-Building Structures
C130 Restoration
C211 Architect—Engineer Services (non-construction)
C212 Engineering Drafting Services
C213 A&E Inspection Services (non-construction)
C214 A&E Management Engineering Services
C215 A&E Production Engineering Services
C216 Marine A&E Services
C219 Other Architect and Engineering Services
R404 Land Surveys, Cadastral Services—non-construction

3. Non-nuclear Ship Repair

Non-nuclear ship repair is included within SIC 3731. Since this SIC includes all ship repair as well as shipbuilding, participating agencies shall use the following FPDS service codes to monitor goal attainment for non-nuclear ship repair: J998 (Ship Repair (Including Overhauls and Conversions) Performed on Non-nuclear Propelled and Nonpropelled Ships East of the 108th Meridian) or J999 (Ship Repair (Including Overhauls and Conversions) Performed on Non-nuclear Propelled and Nonpropelled Ships West of the 108th Meridian).

4. Construction

Goal attainment for construction shall be monitored through the use of the SIC codes identified in Attachment B.

V. Data Collection Requirements

Participating agencies shall maintain and report procurement data to the FPDS in order to determine the level of

small business participation in the four designated industry groups and the ten targeted industry categories for the small business expansion program.

A. Awards in Excess of $25,000

For contract awards in excess of $25,000, the FPDS (1) has information on the SIC code of the procurement and (2) can distinguish awards to small business concerns and small disadvantaged business concerns, as required by section 714(c) of the Small Business Competitiveness Demonstration Program Act of 1988. However, the FPDS reporting requirements are being revised to:

1. Distinguish awards resulting from solicitations issued under the Program from awards resulting from solicitations issued prior to January 1, 1989, in the four designated industry groups. A distinction must be made between contract actions awarded from solicitations issued under the Program and contract actions awarded from solicitations issued prior to January 1, 1989.

2. Distinguish emerging small business firms from other small businesses. Participating agencies must make a good faith effort to award not less than 15 percent of the dollar value of awards in the four designated industry groups to emerging small businesses.

3. Distinguish awards to emerging small business firms in the small business reserve program. Participating agencies must reserve for exclusive competition among emerging small business concerns all contracts of $25,000 or less in the four designated industry groups or a greater amount set by OFPP if the 15 percent goal is not attained. Emerging small businesses can also receive awards above the small business reserve threshold.

4. Provide the size of the small business concern in terms of number of employees or dollar volume of sales for awards in the four designated industry groups and the ten targeted industry categories. Section 714(c) of the Small Business Competitiveness Demonstration Program Act requires each participating agency to collect data pertaining to the size of the small business concern receiving any award for services in the four designated industry groups and products or services in the ten targeted industry categories. The number of employees will be based on the average of the pay periods for the last twelve months. The volume of sales will be based on the average annual gross revenue for the last three fiscal years (see FAR 19.101).

5. Limit A&E services to contracts awarded under the qualification-based selection procedures of 40 U.S.C. 541 *et seq.* (the "Brooks A–E Act").

6. Specific details outlining the FPDS changes have been included in an amendment to the October 1988 FPDS Reporting Manual.

B. Awards of $25,000 or Less

During the term of the Program, each award of $25,000 or less made by a participating agency for the procurement of a service in the four designated industry groups shall be reported to the Federal Procurement Data Center in the same manner as if the award was in excess of $25,000. This means that all applicable data collected in the FPDS via the Individual Contract Action Report (SF 279), or agencies' equivalent computer-generated format, shall be reported for these purchases. It should be noted that awards of $500 or less are not reportable to the FPDS.

Specific details outlining the FPDS changes have been included in an amendment to the October 1988 FPDS Reporting Manual.

C. Subcontracting Activity

1. The OFPP Administrator is required to develop and implement a simplified system to collect data on the participation of small business concerns (including small business concerns owned and controlled by socially and economically disadvantaged individuals) as other than prime contractors. The system shall collect subcontract data regarding prime contracts for A&E services (including surveying and mapping) that are procured under 40 U.S.C. 541 *et seq.* (the "Brooks A–E Act"). The system is applicable to the Environmental Protection Agency, the National Aeronautics and Space Administration, the United States Army Corps of Engineers (Civil Works), and the Department of Energy.

2. A separate Subcontract Reporting System Test Plan and Reporting Form has been developed to implement this requirement.

Attachment A

Clause No. 1

Insert the following provision (clause no. 1) in full text in all solicitations issued by the participating agencies under the Small Business Competitiveness Demonstration Program for the four designated industry groups. Insert this clause as Alternate I in addition to the clause at FAR 52.219–1.

Small Business concern representation for the Small Business Competitiveness Demonstration Program (August 1989)

(a) *Definition.*

"Emerging small business", as used in this solicitation, means a small business concern whose size is no greater than 50 percent of the numerical size standard applicable to the standard industrial classification code assigned to a contracting opportunity.

(b) (Complete only if Offeror has certified itself under the clause at FAR 52.219–1 as a small business concern under the size standards of this solicitation.)

The Offeror represents and certifies as part of its offer that it _____is, _____is not an emerging small business.

(c) (Complete only if the Offeror is a small business or an emerging small business, indicating its size range.)

Offeror's number of employees for the past twelve months (check this column if size standard stated in solicitation is expressed in terms of number of employees) or Offeror's average annual gross revenue for the last three fiscal years (check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)

No. of employees	Avg. annual gross revenues
_____50 or fewer.	_____$1 million or less
_____51—100.	_____$1,000,001—$2 million
_____101—250.	_____$2,000,001—$3.5 million
_____251—500.	_____$3,500,001—$5 million
_____501—750.	_____$5,000,001—$10 million
_____751—1,000.	_____$10,000,001—$17 million
_____Over 1,000.	_____Over $17 million

(End of clause)

Clause No. 2

A. Insert the following provision (Clause no. 2) in full text in all solicitations and resulting contracts restricted to emerging small businesses pursuant to paragraph III. D. 3.

Notice of emerging Small Business set-aside (Dec 1988)

Offers or quotations under this acquisition are solicited from emerging small business concerns only. Offers that are not from an emerging small business shall not be considered and shall be rejected.

(End of provision)

B. When using other than small purchase procedures, insert the clause at 52.219–14 in all solicitations and resulting contracts restricted to emerging small businesses.

Clause No. 3

Insert the following provision (clause no. 3) in full text in all solicitations issued in each of the ten targeted industry categories under the Small Business Competitiveness Demonstration Program that is expected to result in a contract award in excess of $25,000. Insert this clause as Alternate II in addition to the clause at FAR 52.219–1.

Small Business size representation for targeted industry categories under the Small Business Competitiveness Demonstration Program (August 1989)

(Complete only if the Offeror has certified itself under the clause at FAR 52.219–1 to be a small business concern under the size standards of this solicitation.)

Offeror represents and certifies as follows:

Offeror's number of employees for the past twelve months (check this column if size standard stated in solicitation is expressed in terms of number of employees) or Offeror's average annual gross revenue for the last three fiscal years (check this column if size standard stated in solicitation is expressed in terms of annual receipts). (Check one of the following.)

No. of employees	Avg. annual gross revenues
_____50 or fewer.	_____$1 million or less
_____51–100	_____$1,000,001–$2 million
_____101–250.	_____$2,000,001–$3.5 million
_____251–500.	_____$3,500,001–$5 million
_____501–750.	_____$5,000,001–$10 million
_____751–1,000.	_____$10,000,001–$17 million
_____Over 1,000.	_____Over $17 million

(End of clause)

Attachment B

Report on Small Business Participation Under the Small Business Competitiveness Demonstration Program for Designated Industry Groups

Fiscal Year _____
Quarter _____
Agency: _____
Subagency (if applicable) _____

Designated groups	Total US business actions/dollars	Small business actions/dollars[1]	Percentage of dollars	Small disadvantaged business actions/dollars	Percentage of dollars	Emerging small business actions/dollars	Percentage of dollars
I. Construction, excluding dredging (Dollars in Thousands; Percentages in Whole Numbers)							
SIC Group 15:							
1521							
1522							
1531							
1541							
1542							
Subtotal							
SIC Group 16:							
1611							
1622							
1623							
1629							
Subtotal							
SIC Group 17:							
1711							
1721							
1731							
1741							
1742							
1743							
1751							
1752							
1761							
1771							
1781							
1791							
1793							
1794							
1795							
1796							
1799							
Subtotal							
Grand Total							
II. Refuse Systems and Related Services (Dollars in Thousands, Percentages in Whole Numbers)							
PSC S205							
Total							
III. Architectural and Engineering Services, including mapping and surveying (Dollars in Thousands; Percentages in Whole Numbers)							
SIC 7389:							
PSC T002							
PSC T004							
PSC T008							

Designated groups	Total US business actions/dollars	Small business actions/dollars[1]	Percentage of dollars	Small disadvantaged business actions/dollars	Percentage of dollars	Emerging small business actions/dollars	Percentage of dollars
PSC T009							
PSC T014							
Subtotal							
SIC 8711 or 8712 or 8713:							
PSC C111							
PSC C112							
PSC C113							
PSC C114							
PSC C115							
PSC C116							
PSC C117							
PSC C118							
PSC C119							
PSC C121							
PSC C122							
PSC C123							
PSC C124							
PSC C129							
PSC C130							
PSC C211							
PSC C212							
PSC C213							
PSC C214							
PSC C215							
PSC C216							
PSC C219							
PSC R404							
Subtotal							
Grand Total							
IV. Non-nuclear Ship Repair (Dollars in Thousands; Percentages in Whole Numbers)							
SIC 3731:							
PSC J990							
PSC J999							
Total							

[1] Small Business Dollars include dollars to Emerging Small Business.

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BILLING CODE 3110–01–M

Subcontracting Reporting System Test Plan and Reporting Form

AGENCY: Executive Office of the President, Office of Management and Budget (OMB), Office of Federal Procurement Policy.

ACTION: The Office of Federal Procurement Policy (OFPP) is requesting comments on a proposed Subcontract Reporting System Test Plan and Reporting Form that provide guidance on reporting subcontracting activity under the Small Business Competitiveness Demonstration Program.

SUMMARY: The proposed Subcontract Reporting System Test Plan and Reporting Form are being issued to implement Section 202(d) of the Small Business Credit and Business Opportunity Enhancement Act of 1992, (Public Law 102–366). Section 202(d) requires the Administrator for Federal Procurement Policy to develop and implement a simplified system to collect data on the participation of small business concerns (including small business concerns owned and controlled by socially and economically disadvantaged individuals) as other than prime contractors. The system shall collect subcontract data regarding prime contracts for architectural and engineering (A&E) services (including surveying and mapping) that are procured under 40 U.S.C. 541 *et seq.* (the Brooks A-E Act). The system is applicable to the Environmental Protection Agency, the National Aeronautics and Space Administration, the United States Army Corps of Engineers (Civil Works), and the Department of Energy.

The primary purpose of this proposed new simplified reporting system is to demonstrate that the actual rate of small business participation on A&E prime contracts is substantially higher than is now being reflected in data captured by the Government's existing procurement data system. Also, this new system is intended to collect subcontracting data under a broader range of A&E contract awards than are covered by the existing reporting requirements of Public Law 95–507.

COMMENT DATE: Comments must be received on or before May 17, 1993.

ADDRESSES: Comments should be sent to Dr. Allan V. Burman, Administrator, Office of Federal Procurement Policy, Office of Management and Budget, 725 17th Street, NW., room 9001, Washington, DC 20503.

COMMENTS ON THE INFORMATION COLLECTION REQUIREMENTS: The test reporting system requires Federal prime contractors (other than small business and small disadvantaged business firms) to collect and report subcontract activity in support of Federal prime contracts for A&E services (including surveying and mapping). This information collection may place a substantial reporting burden on the Federal prime contractors participating in the reporting system. Comments are solicited on the impact of this reporting requirement on existing industry subcontract data collection systems.

Comments on the information collection requirements contained in the

Subcontract Reporting System Test Plan and Reporting Form should be submitted both to the OFPP Administrator at the above address and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503, Attention: Peter Weiss, Desk Officer for the Federal Acquisition Regulation.

FOR FURTHER INFORMATION CONTACT: Linda G. Williams, Deputy Associate Administrator, (202) 395–3302.

SUPPLEMENTARY INFORMATION:

A. Background

Pursuant to the Small Business Act, prime contractors and subcontractors (except small business firms) that receive one or more contracts over $500,000 ($1 million for construction) are required to submit a subcontracting plan with goals for using small business and small disadvantaged business concerns as subcontractors under Federal prime contracts, and to report accomplishments against the goals. Concerns have been expressed that small business firms actually receive more subcontracting opportunities than are being reported under the existing reporting system. As part of the Small Business Competitiveness Demonstration Program, OFPP is required to develop and implement a simplified reporting system to test the rate of small business and small disadvantaged business participation at the subcontract level under Federal prime contracts for A&E services (including surveying and mapping).

B. Regulatory Flexibility Act

This reporting system will not have a significant impact on small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq., and, therefore, no Regulatory Impact analysis has been prepared.

The system seeks to measure the amount of small business participation in subcontracts. The reporting requirements of the system will be imposed on large businesses and, as such, there is no cost to small businesses.

C. Executive Order No. 12291

This reporting system has been reviewed in accordance with the objectives and criteria of Executive Order No. 12291. The system will not result in any of the economic or regulatory impacts associated with a major rule. The system will not have an annual effect on the economy of $100 million or more and will not result in a major increase in cost for consumers, individual industries, State and local government agencies, or geographic regions and would not have an adverse effect on competition, employment, investment, productivity, innovation, and the ability of United States based industries to compete with foreign-based enterprises in domestic or export markets.

D. Paperwork Reduction Act

The information collection requirements for this reporting system have been submitted to the Office of Management and Budget for approval.

Dated: April 8, 1993.

David Baker,

Associate Administrator, Office of Federal Procurement Policy.

MEMORANDUM FOR SELECTED AGENCY SENIOR PROCUREMENT EXECUTIVES

(See Attached List)

April 8, 1993.

FROM: David Baker for Allan V. Burman, Administrator

SUBJECT: Proposed Subcontract Reporting System Test Plan and Reporting Form—Small Business Competitiveness Demonstration Program

1. *Purpose.* This memorandum provides policy direction to the Environmental Protection Agency, the National Aeronautics and Space Administration, the United States Army Corps of Engineers (Civil Works) and the Department of Energy for implementation of Section 202(d) of the Small Business Credit and Business Opportunity Enhancement Act of 1992, (Public Law 102–366), that establishes the requirement for a simplified Subcontract Reporting System.

2. *Authority.* The requirement for a simplified Subcontract Reporting System is established pursuant to Section 202(d) of Public Law 102–366, and Section 15 of the Office of Federal Procurement Policy Act, 41 U.S.C. 413, which provides for the testing of innovative procurement methods and procedures.

3. *Background.* Pursuant to the Small Business Act, prime contractors and subcontractors (except small business firms) that receive one or more contracts over $500,000 ($1 million in construction) are required to submit a subcontracting plan with goals for using small business and small disadvantaged business concerns as subcontractors under Federal prime contracts and to report accomplishments against the goals. Concerns have been expressed that the current reporting system does not provide information on the full range of participation by small business firms in the Federal procurement process. As part of the Small Business Competitiveness Demonstration Program, OFPP is to develop and implement a simplified system to collect data on the participation of small business concerns (including small business concerns owned and controlled by socially and economically disadvantaged individuals) as other than prime contractors. The system shall collect subcontract data regarding prime contracts for architectural and engineering (A&E) services (including surveying and mapping) that are procured under 40 U.S.C. 541 *et seq.* (the Brooks A-E Act).

4. *Policy.* The primary purpose of this new simplified Subcontract Reporting System is to demonstrate that the actual rate of small business participation on A&E prime contracts is substantially higher than is now being reflected in data captured by the Government's existing procurement data system. The procedures for implementing the test reporting system are set forth in the attached test plan.

5. *Implementation.* The participating agencies are required to implement the attached test plan commencing on January 1, 1993. Since this is a limited test, these requirements will not be implemented in the Federal Acquisition Regulation.

6. *Expiration Date.* The simplified Subcontract Reporting System shall be in effect through September 30, 1996.

Attachment: c. Selected OSDBU Directors, Selected FPDS Policy Advisory Board Members.

Selected Agency Senior Procurement Executives

Mr. Silas B. Fisher, Director, Office of Procurement and Assistance Management, Department of Energy, Room 5B080, 1000 Independence Avenue, SW.,Washington, DC 20585.

Mr. Michael Bower, Acting Director, Procurement and Contracts Management Division (PM–214), Environmental Protection Agency, 401 M Street, SW, Room 805, Washington, DC 20460.

Ms. Deidre Lee, Acting Associate Administrator for Procurement, NASA Headquarters, Room 425, Washington, DC 20546.

Mr. Donald Yockey, Under Secretary of Defense for Acquisition, Department of Defense, Room 3E933 (Pentagon), Washington, DC 20301.

Honorable Stephen K. Conver, Assistant Secretary of the Army (Research, Development, and Acquisition), Department of the Army, Room 2E672 (Pentagon), Washington, DC 20310.

Selected OSDBU Directors

Mr. Leonel V. Miranda, Director, Office of Small and Disadvantaged Business Utilization, Department of Energy, 1707 H Street, NW., Room 904, Washington, DC 20585.

Mr. Leon Hampton, Director, Office of Small and Disadvantaged Business Utilization, Environmental Protection Agency, 401 M Street, SW. (A149C), Washington, DC 20460.

Mr. Ralph C. Thomas, Assistant Administrator, Office of Small and Disadvantaged Business Utilization, National Aeronautics and Space Administration (Code K), Washington, DC 20546.

Mr. Dave Buettner, Director, Office of Small and Disadvantaged Business Utilization, U.S. Army Corps of Engineers, 20

Massachusetts Avenue, NW., Washington, DC 20314–1000.

Selected FPDS Policy Advisory Board Members

Mr. James Nelson, Director, Procurement Management Systems and Analysis Div. (MA–432), Department of Energy, 1000 Independence Avenue, SW., Washington, DC 20585.

Mr. Edward Murphy, Procurement and Contracts Management Division (PM214F), Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Mr. Herb Baker, Procurement Management Div (Code HM), National Aeronautics and Space Administration, Washington, DC 20546.

Mr. Carl Brotman, Office of the Deputy Under Secretary of Defense for Acquisition Management, Room 3C838 (Pentagon), Washington, DC 20301.

Proposed Subcontract Reporting System Test Plan, Small Business Competitiveness Demonstration Program

I. Purpose

This document implements Section 202(d) of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Public Law 102–366). Section 202(d) requires the Administrator for Federal Procurement Policy to develop and implement a simplified system to collect data on the participation of small business concerns (including small business concerns owned and controlled by socially and economically disadvantaged individuals) as other than prime contractors. The system shall collect subcontract data regarding prime contracts for architectural and engineering (A&E) services (including surveying and mapping) that are procured under 40 U.S.C. 541 *et seq.* (the Brooks A–E Act).

The primary purpose of this proposed new simplified reporting system is to demonstrate that the actual rate of small business participation on A&E prime contracts is substantially higher than is now being reflected in data captured by the Government's existing procurement data system. Also, this new reporting system is intended to collect subcontracting data under a broader range of A&E contract awards than are covered by the existing reporting requirements of Public Law 95–507.

This new simplified reporting system will cover subcontract activity through the second tier under A&E prime contracts and be applicable to four participating agencies.

II. Authority

The requirement for a simplified subcontract reporting system (the System) is established pursuant to section 202(d) of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Public Law 102–366), and section 15 of the Office of Federal Procurement Policy Act, 41 U.S.C. 413, which provides for the testing of innovative procurement methods and procedures.

III. Program Requirements

A. Applicability

The System shall be in effect from January 1, 1993 through September 30, 1996 and shall include subcontract data under A&E prime contracts awarded under the Brooks A–E Act from solicitations issued during the same period. The System shall be applicable to data collected from prime contractors, excluding small business and small disadvantaged business firms, that receive a prime contract for A&E services (including surveying and mapping) under the Brooks A–E Act with an anticipated award value over $100,000 and which has the possibility for subcontracting opportunities. (See subsections (C) and (D) below). The prime contractors shall report information on subcontract awards over $25,000 through the second tier that are directly needed for prime contract performance, irrespective of the product or service provided under the subcontract.

B. Covered Agencies

1. The following agencies are covered by the System:

a. the Environmental Protection Agency,

b. the National Aeronautics and Space Administration,

c. the United States Army Corps of Engineers (Civil Works), and

d. the Department of Energy.

2. All contracting offices at the covered agencies shall report information from prime contractors to the System.

C. Covered Designated Industry Group

Subcontract awards under prime contracts in the following designated industry group are to be reported under the System: architectural and engineering (A&E) services (including surveying and mapping) under standard industrial classification (SIC) codes 7389, 8711, 8712, or 8713 (limited to FPDS service codes C111 through C216, C219, T002, T004, T008, T009, T014, and R404) awarded under the Brooks A–E Act.

D. Small Business Goal Determination

The value of other than prime contract awards to small business concerns shall count toward determining whether the small business participation goal under the Small Business Competitiveness Demonstration Program is attained for A&E services.

E. Contract Clause for Procurements Covered by the System

The following clause shall be inserted in contracts and solicitations covered by the System that are issued from January 1, 1993 through September 30, 1996 with an estimated contract value over $100,000 and which have the possibility for subcontracting opportunities. The clause is not applicable to small business and small disadvantaged business firms.

Subcontract Reporting under the Small Business Competitiveness Demonstration Program (October 1992)

(a) The Contractor shall submit a completed Form XXX in accordance with instructions on the Form.

(b) The Contractor shall include subparagraph (a) of this clause in subcontracts with an estimated value over $25,000 awarded under this contract, excluding subcontracts with small business and small disadvantaged business firms, non-profits, educational institutions, and state and local governments. The Contractor shall also include this subparagraph (b), or its equivalent, in any such subcontract so that these requirements will be binding upon subcontracts awarded through the second tier.

(c) The Contractor shall include the prime contract number in its subcontracts and require its subcontractors through the second tier (except small business and small disadvantaged business firms, non-profits, educational institutions, and state and local governments) to include both the prime contract number and their subcontract number in their subcontracts. (Note: The prime contract number shall be the identifier used to track all subcontract activity under the prime contract.)

IV. Reporting

A. Prime Contractor Responsibility

The attached flow chart (Attachment A) indicates the responsibility of the Federal prime contractor for collecting and reporting subcontract data by tiers.

B. Forms

1. A separate reporting form has been designed to collect data from contractors in support of the System (see Attachment B - Form XXX). The instructions require the prime contractors to report the data, on a quarterly basis, to the covered agencies within 30 days after the end of the

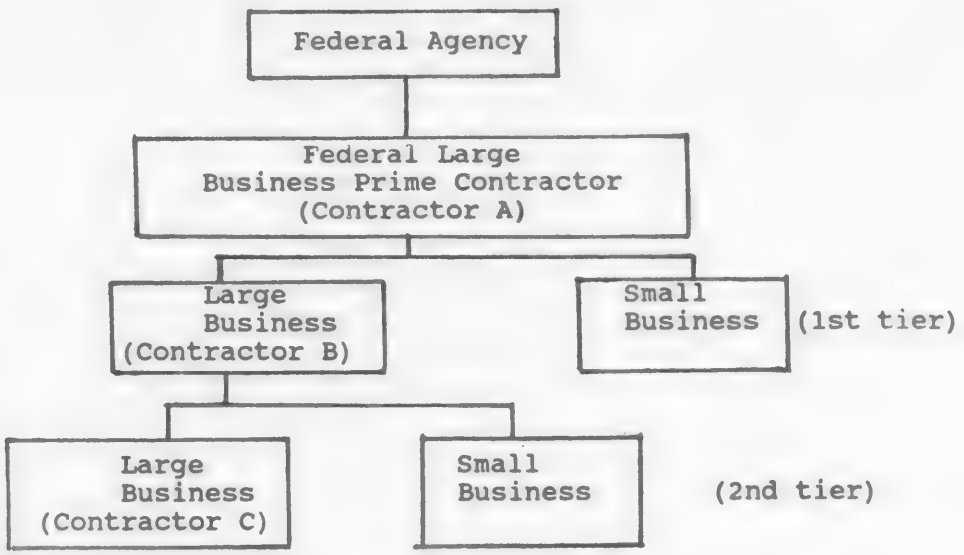
reporting period. The Federal prime contractor shall establish a reporting schedule for its subcontractors such that the consolidated reports can be submitted to the covered agency within 30 days.

2. Copies of Form XXX will be forwarded to the covered agencies by OFPP. Contracting officials shall be responsible for providing the original copy of Form XXX to the prime contractors. The Federal prime contractor shall be responsible for ensuring that its subcontractors in support of the prime contract receive copies of the Form. Each subcontractor (other than small business and small disadvantaged business firms) shall also ensure that its subcontractors receive copies of the Form.

C. Determining Small Business Participation Rates

Each covered agency's Office of Small and Disadvantaged Business Utilization (OSDBU), or other designated office, shall be responsible for establishing a procedure for the collection of the hardcopy Forms XXX from each contracting office in order to determine small business participation at the subcontract level. The prime A&E contract and subcontracting dollars to small business shall be added to derive at the total small business participation level. This information shall be reported to OFPP in the agency's quarterly reports under the Demonstration Program. The information on subcontracting that was added to the prime A&E contract dollars shall be provided to OFPP as backup data with the agency's quarterly reports.

Attachment A—Flowchart for Reporting Subcontracting Activity, Subcontract Reporting System Test Plan, Small Business Competitiveness Demonstration Program



- The Federal prime contractor (other than a small business or small disadvantaged business firm) receives a contract in excess of $100,000 for A&E services (including surveying and mapping) under Brooks A–E Act procedures.
- The Federal prime contractor shall report information on subcontracts awards over $25,000 through the second tier that are directly needed for prime contract performance, irrespective of the product or service provided under the subcontract.
- The Federal prime contractor is responsible for ensuring that data concerning subcontracting activity in support of the prime contract is collected and reported in accordance with instructions on Form XXX.
- Subcontracting activity is reported by the first tier subcontractor (other than small business or small disadvantaged business subcontractors) to the Federal prime contractor rather than to the Federal agency.
- The Federal prime contractor must include the prime contract number in each subcontract and require the subcontractor (other than a small business and small disadvantaged business subcontractor) to include both the prime contract number and its subcontract number in its subcontracts.
- An example of a Federal prime contractor's responsibility for collecting and reporting subcontracting activity under a Federal prime contract:

—Contractor A is a Federal prime contractor (other than a small business or small disadvantaged business firm) who received a prime contract over $100,000 from a Federal agency for A&E services (including surveying and mapping) under the Brooks A–E Act.

—Contractor A subcontracts part of the effort to other large (Contractor B) or small business firms. This is considered the 1st tier of subcontracting in support of the prime contract. Contractor A is responsible for reporting its subcontracting activity in Item 11 on Form XXX.

—Contractor B is a subcontractor (other than a small business or small disadvantaged business firm) who received a subcontract in excess of $25,000 from contractor A, and subcontracts part of the effort to other large (Contractor C) or small business firms. This is considered the 2nd tier of subcontracting. Contractor B is responsible for reporting its subcontracting activity to Contractor A using Item 11 on Form XXX.

—Contractor A is responsible for aggregating the subcontracting data and reporting the information in Item 12 on Form XXX.

Attachment B—Subcontract Activity for Individual Contracts—Small Business Competitiveness Demonstration Program (This Form Shall Not Be Completed by Small Business Firms)

Part I. To Be Completed by Federal Contracting Activity

1. Participating Agency
2. Contracting Activity
3. Federal Prime Contract Number
4. Sic Code _____

Part II. To Be Completed by Federal Prime Contractors and/or Subcontractors

5. Reporting Contractor/Subcontractor

_____

_____

6. Date: _____
7. Reporting Entity's Contract Number

_____

8. Reporting Entity's Tier Level

_____

9. Reporting Period:
Fiscal Year _____
[ ] Oct. 1–Dec. 31
[ ] Jan. 1–March 31
[ ] April 1–June 30
[ ] July 1–Sept. 30
10. Report Is:
[ ] Regular
[ ] Final
[ ] Revision
11. Subcontract Awards This Period (Rounded Whole Dollars)

	Dollars
(a) Small Business (Including Small Disadvantaged) ($ Amount of 11(c))	
(b) Large Business ($ Amount of 11(c))	
(c) Total (Sum of 11(a) and 11(b))	
(d) Small Disadvantaged Business of ($ Amount of 11(c))	

Part III. To Be Completed by Federal Prime Contractors Only

12. Cumulative Subcontract Awards (by Tier)

Tier	(a) Small business (Incl. disadvantaged)	(b) Large business	(c) Cumulative total	(d) Small disadvantaged business (dollars)
1st				
2nd				
Total				

Part IV. To Be Completed by Federal Prime Contractors and/or Subcontractors

13. Name/Title

_____

Signature

_____

Telephone Number

_____

14. Report Approved by:

_____

Name and title

_____

Signature

_____

Attachment B—General Instructions, Subcontract Activity for Individual Contracts

1. This form collects subcontract data from prime contractors (except small business and small disadvantaged business firms) that receive a Federal contract over $100,000 for architectural and engineering (A&E) services (including surveying and mapping) under Brooks A–E Act procedures. This data collection is required by the Subcontract Reporting System Test Plan established pursuant to section 202(d) of the Small Business Credit and Business Opportunity Enhancement Act of 1992 (Pub. L. 102–366).

The form also shall be used by the prime contractor to collect subcontract data from its first tier subcontractors (excluding small business and small disadvantaged business firms) that receive a subcontract over $25,000 in support of the Federal prime contract.

2. Federal prime contractors are responsible for collecting and reporting subcontract activity through the second tier in support of the prime A&E contract irrespective of the product or service provided under the subcontract.

3. Federal prime contractors are also required to include the prime contract number in each of their subcontracts and to require their subcontractors (except small business and small disadvantaged business firms) to include both the prime contract number and the subcontract number in their subcontracts. The prime contract number shall be the identifier used by the large business Federal prime contractor to track all subcontract activity under the prime contracts covered by the System.

4. Federal prime contractors shall submit the report quarterly, within 30 days after the end of each reporting period. The Federal prime contractor must establish a reporting schedule for its subcontractors such that the reports can be consolidated and submitted to the Federal agency with 30 days. A negative report shall be submitted when there has been no subcontracting activity or there has been no change from the last reporting period.

5. All dollar amounts shall be rounded to the nearest whole dollar.

6. Only subcontracts involving performance within the United States, its possessions, Puerto Rico, and the Trust Territory of the Pacific Islands shall be included in this report.

7. This report shall not be submitted by small business and small disadvantaged business firms.

8. Copies of Form XXX are available from the contracting office awarding the prime contract. For subcontractors, the Form is available from the contractor who awarded the subcontract.

Specific Instructions

Part I. To Be Completed by Federal Department or Agency

Item 1. Enter the name of the Federal Department or Agency designated to participate in the test reporting system.

Item 2. Enter the name and address of the contracting activity awarding the Federal prime contract.

Item 3. Enter the Federal prime contract number.

Item 4. Enter the standard industrial classification (SIC) number of the prime A&E contract, i.e. SIC codes 7389, 8711, 8712, or 8713.

Part II. To Be Completed by Federal Prime Contractors and/or Subcontractors

Item 5. Enter the name and address of the entity completing the form. The form is a multi-purpose form and shall be used by Federal prime contractors and subcontractors to report their subcontract activity.

Item 6. Enter the date that the form is prepared.

Item 7. Enter the reporting entity's contract number. If this report is from a subcontractor, enter the subcontract number.

Item 8. Enter the reporting entity's tier level. Federal prime contractors and subcontractors through the second tier (in relation to the Federal prime contract) shall identify their tier level to their subcontractors. As an example, when the Federal prime contractor subcontracts part of the prime contract effort, the prime contractor shall notify the subcontractor that this is the first tier of subcontracting. The first tier subcontractor shall, in turn, notify its subcontractors that they are the second tier subcontractors.

Item 9. Enter the Federal Fiscal Year and check the appropriate block for the period covered by the report.

Item 10. Check whether the report is a regular quarterly report, final report, or a revision to a prior report. If the report is a regular quarterly report which contains revisions to a previously submitted report, check revision. Check final report only if the reporting prime contractor/subcontractor has completed all work under the prime contract/subcontract.

Item 11. Enter the dollar amount for subcontract awards to small business (including small disadvantaged business) and large business (excluding subcontracts to non-profits, educational institutions, and state and local governments) subcontractors during the reporting period. Amounts reported include direct awards only. Enter zero if no subcontract awards have been made during the reporting period.

Item 11(d). Enter the dollar amount for subcontract awards to small disadvantaged business subcontractors. This figure is a portion of the total subcontract dollars in 11(c).

Part III. To Be Completed by Federal Prime Contractors Only

Item 12. Enter the cumulative dollar amount for subcontract awards to small business (including small disadvantaged business) and large business through the second tier of subcontracting related to the prime contract. This figure is the sum of all subcontract dollars reported by the large business subcontractors since award of the prime contract. (For example, the Federal prime contractor shall report in the 1st tier line, its cumulative direct subcontract awards. Under the 2nd tier line, the Federal prime contractor shall include all subcontract awards made by the 1st tier subcontractor.)

Item 12(d). Enter the cumulative dollar amount for subcontract awards to small disadvantaged business subcontractors. This figure is a portion of the total subcontract dollars in 12(c) for each respective tier.

Part IV. To Be Completed by Federal Prime Contractors and/or Subcontractors

Item 13. Enter the name, title, signature and telephone number of the person completing the report.

Item 14. Enter the name, title, and signature of the approving official. The approving official shall be the chief executive officer or in the case of a separate division or plant, the senior individual responsible for the overall division/plant operations.

Definitions

1. *Federal prime contractor,* as used for this test reporting system, is a business firm (other than a small business or small disadvantaged business) who is awarded a Federal prime contract for A&E services (including surveying and mapping) under the Brooks A–E Act by one of the participating agencies (EPA, NASA, Army Corps of Engineers (Civil Works), and DOE).

2. *Subcontract* means a contract; purchase order, amendment, or other legal obligation executed by a prime contractor or subcontractor calling for supplies or services required for the performance of the prime contract or subcontract. Purchases from a corporation, company, or subdivision which is owned or controlled by the reporting prime contractor are not considered "subcontracts" and shall not be included in this report.

3. *Direct Subcontract Awards* are those which are identified with the performance of a specific government contract, including allocable parts of awards for materials which are to be incorporated into products under more than one contract.

Submittal Addresses for Prime Contractors

For DOD Contractors:

All Federal prime contractors (other than small business and small disadvantaged business firms) shall distribute the original and copies as follows:

(1) The original of each report shall be sent directly to the contracting officer at the activity awarding the prime contract.

(2) Copies shall be submitted to: Headquarters, U.S. Army Corps of Engineers, Director, Office of Small and Disadvantaged Business Utilization, 20 Massachusetts Avenue, NW., Washington, DC 20314–1000.

For Civilian Agency Contractors:

The original of each report shall be sent directly to the contracting officer at the activity awarding the prime contract. A copy of each report shall be sent as follows:

NASA—NASA Headquarters, Procurement Systems Division (Code HM), Washington, DC 20546.

DOE—Office of Small and Disadvantaged Business Utilization, Washington, DC 20585.

EPA—Office of Small and Disadvantaged Business Utilization, Washington, DC 20460.

[FR Doc. 93–8946 Filed 4–15–93; 8:45 am]

BILLING CODE 3110–01–M

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

SUMMARY: In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. chapter 35), the Railroad Retirement Board has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s):

(1) *Collection title:* Continuing Disability Report.

(2) *Form(s) submitted:* G–254.

(3) *OMB Number:* N.A.

(4) *Expiration date of current OMB clearance:* Three years from date of OMB approval.

(5) *Type of request:* Reinstatement of a previously approved collection for which approval has expired.

(6) *Frequency of response:* On occasion.

(7) *Respondents:* Individuals or households, businesses or other for-profit.

(8) *Estimated annual number of respondents:* 1,500.

(9) *Total annual responses:* 1,500.

(10) *Average time per response:* .41533 hour.

(11) *Total annual reporting hours.* 623.

(12) *Collection description:* The report obtains information about a disabled annuitant's employment and earnings. Under the RRA, a disability annuity can be reduced or not paid, depending on the amount of earnings and type of work performed.

Additional Information or Comments

Copies of the form and supporting documents can be obtained from Dennis Eagan, the agency clearance officer (312–751–4693). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 N. Rush Street,

Chicago, Illinois 60611–2092 and the OMB reviewer, Laura Oliven (202–395–7316), Office of Management and Budget, room 3002, New Executive Office Building, Washington, DC 20503.

Dennis Eagan,

Clearance Officer.

[FR Doc. 93–8931 Filed 4–15–93; 8:45 am]

BILLING CODE 7905–01–M

RESOLUTION TRUST CORPORATION

Coastal Barrier Improvement Act; Property Availability; Denton County-Lakeview, Denton County, TX

AGENCY: Resolution Trust Corporation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the property known as the Denton County-Lakeview property, located in Denton, Denton County, Texas, is affected by section 10 of the Coastal Barrier Improvement Act of 1990, as specified below.

DATES: Written notices of serious interest to purchase or effect other transfer of the property may be mailed of faxed to the RTC until July 15, 1993.

ADDRESSES: Copies of detailed descriptions of the property, including maps, can be obtained from or are available for inspection by contacting the following person: Mr. Steven Reid, Resolution Trust Corporation, Dallas Field Office, 3500 Maple Avenue, Riverchon Plaza, 18th Floor, Dallas, TX 75219–3935, (214) 443–4738; Fax (214) 443–4825.

SUPPLEMENTARY INFORMATION: The Denton County-Lakeview property is located near Lake Lewisville on the south side of Blagg Road at Trinity Road in Denton, Texas. Approximately 40 acres of the property is situated in a floodplain and the site is adjacent to property managed by the U.S. Army Corps of Engineers for conservation purposes. The property is covered property within the meaning of section 10 of the Coastal Barrier Improvement Act of 1990, Public Law 101–591 (12 U.S.C. 1441a–3).

Characteristics of the property include: The Denton County-Lakeview property consists of approximately 238.43 acres of undeveloped land. The vegetation on the site ranges from dense to open grassy areas. The topography is gently sloping and the soil has a moderate to low permeability. This property is within the floodplain of a tributary of the Trinity River.

Property size. Approximately 238.43 acres.

Written notice of serious interest in the purchase or other transfer of the property must be received on or before July 15, 1993 by the Resolution Trust Corporation at the address stated above.

Those entities eligible to submit written notices of serious interest are:

1. Agencies or entities of the Federal government;
2. Agencies or entities of State or local government; and
3. "Qualified organizations" pursuant to section 170(h)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(3)).

Written notices of serious interest to purchase or effect other transfer of the property must be submitted by July 15, 1993 to Mr. Steven Reid at the above ADDRESSES and in the following form:

Notice of Serious Interest

RE: Denton County-Lakeview
Federal Register Publication Date: April 16, 1993.

1. Entity name.
2. Declaration of eligibility to submit Notice under criteria set forth in Coastal Barrier Improvement Act of 1990, P.L. 101–591, Section 10(b)(2), (12 U.S.C. 1441a–3(b)(2)).
3. Brief description of proposed terms of purchases or other offer (e.g., price and method of financing).
4. Declaration by entity that it intends to use the property primarily for wildlife refuge, sanctuary, open space, recreational, historical, cultural, or natural resource conservation purposes.
5. Authorized Representative (Name/Address/Telephone/Fax).

Dated: April 9, 1993.

Resolution Trust Corporation.

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93–8956 Filed 4–15–93; 8:45 am]

BILLING CODE 6714–01–M

Coastal Barrier Improvement Act; Property Availability; Hunter's Glen at Jefferson, Morris County, NJ

AGENCY: Resolution Trust Corporation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the property known as Hunter's Glen at Jefferson, located in Jefferson Township, Morris County, New Jersey, is affected by section 10 of the Coastal Barrier Improvement Act of 1990, as specified below.

DATES: Written notices of serious interest to purchase or effect other transfer of the property may be mailed or faxed to the RTC until July 15, 1993.

ADDRESSES: Copies of detailed descriptions of the property, including maps, can be obtained from or are available for inspection by contacting the following person: Mr. Randall McRoberts, Resolution Trust Corporation, c/o Midland Asset Management, 210 West 10th Street, Kansas City, MO 64105, (816) 435–3600; Fax (816) 412–2326.

SUPPLEMENTARY INFORMATION: The Hunter's Glen at Jefferson property is located at Route 15 and Compton Gobel Road in Jefferson Township, New Jersey. This undeveloped property is within the boundary of a Sole Source Aquifer designated by the Environmental Protection Agency. The site also contains wetlands and is adjacent to lands managed by the Jersey City Department of Water for natural resource conservation purposes. The property is covered property within the meaning of section 10 of the Coastal Barrier Improvement Act of 1990, Public Law 101–591 (12 U.S.C. 1441a–3).

Characteristics of the property include. The Hunter's Glen at Jefferson property consists of approximately 840 acres of wooded, steeply sloped areas, including over 60 acres of wetlands. The topography of the site is very hilly with elevations that range from 980 feet to 1,250 feet above mean sea level. This property is adjacent to a watershed area managed by the Jersey City Department of Water for the Musconetcong and the Rockaway River Watersheds.

Property size. Approximately 840 acres.

Written notice of serious interest in the purchase or other transfer of the property must be received on or before July 15, 1993 by the Resolution Trust Corporation at the address stated above.

Those entities eligible to submit written notices of serious interest are:

1. Agencies or entities of the Federal government;
2. Agencies or entities of State or local government; and
3. "Qualified organizations" pursuant to section 170(h)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(3)).

Written notices of serious interest to purchase or effect other transfer of the property must be submitted by July 15, 1993 to Mr. Randall McRoberts at the above ADDRESSES and in the following form:

Notice of Serious Interest

RE: Hunter's Glen at Jefferson
Federal Register Publication Date: April 16, 1993.

1. Entity name.
2. Declaration of eligibility to submit Notice under criteria set forth in Coastal Barrier Improvement Act of 1990, Public Law 101–591, section 10(b)(2), (12 U.S.C. 1441a–3(b)(2)).
3. Brief description of proposed terms of purchase or other offer (e.g., price and method of financing).
4. Declaration by entity that it intends to use the property primarily for wildlife refuge,

sanctuary, open space, recreational, historical, cultural, or natural resource conservation purposes.

5. Authorized Representative (Name/Address/Telephone/Fax).

Dated: April 9, 1993.

Resolution Trust Corporation.

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93–8955 Filed 4–15–93; 8:45 am]

BILLING CODE 6714–01–M

Coastal Barrier Improvement Act; Property Availability; Green Valley, Pima County, AZ

AGENCY: Resolution Trust Corporation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the property known as the Green Valley property, located in Pima County, Arizona, is affected by Section 10 of the Coastal Barrier Improvement Act of 1990, as specified below.

DATES: Written notices of serious interest to purchase or effect other transfer of the property may be mailed or faxed to the RTC until July 15, 1993.

ADDRESSES: Copies of detailed descriptions of the property, including maps, can be obtained from or are available for inspection by contacting the following person: Mr. Jim Skubal, Resolution Trust Corporation, c/o FGB Realty Advisors, Inc., 4725 North Scottsdale Road, Suite 250, Scottsdale, AZ 85251, (602) 970–7759; Fax (602) 947–2777.

SUPPLEMENTARY INFORMATION: The Green Valley property is located northeast of the intersection of Arizona Highway 89 and the Continental-Whitehouse Canyon Road in Green Valley, Arizona. The property is located within the boundary of a Sole Source Aquifer and the site is adjacent to state owned lands managed jointly by the University of Arizona and the Arizona State Land Department. The property is covered property within the meaning of section 10 of the Coastal Barrier Improvement Act of 1990, Public Law 101–591 (12 U.S.C. 1441a–3).

Characteristics of the property include: The Green Valley property consists of approximately 435 43 acres of undeveloped land consisting of native desert vegetation. The site is located within the Upper Santa Cruz and Avra Basin Aquifer, a designated Sole Source Aquifer by the Environmental Protection Agency. Two federally endangered species, the Tumamoc globe-berry and the Sanborn's long-nosed bat, may occur on the property. The eastern boundary of the property adjoins lands belonging to the State of Arizona known as the Santa Experimental Range.

Property size: Approximately 435.43 acres.

Written notice of serious interest in the purchase of other transfer of the property must be received on or before July 15, 1993 by the Resolution Trust Corporation at the address stated above.

Those entities eligible to submit written notices of serious interest are:

1. Agencies or entities of the Federal government;

2. Agencies or entities of State or local government; and

3. "Qualified organizations" pursuant to section 170(h)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(3)).

Written notices of serious interest to purchase or effect other transfer of the property must be submitted by July 15, 1993 to Mr. Jim Skubal at the above ADDRESSES and in the following form:

Notice of Serious Interest

RE: Green Valley

Federal Register Publication Date: April 16, 1993.

1. Entity name.

2. Declaration of eligibility to submit Notice under criteria set forth in Coastal Barrier Improvement Act of 1990, Public Law 101–591, section 10(b)(2), (12 U.S.C. 1441a–3(b)(2)).

3. Brief description of proposed terms of purchase or other offer (e.g., price and method of financing).

4. Declaration by entity that it intends to use the property primarily for wildlife refuge, sanctuary, open space, recreational, historical, cultural, or natural resource conservation purposes.

5. Authorized Representative (Name/Address/Telephone/Fax).

Dated: April 9, 1993.

Resolution Trust Corporation.

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93–8953 Filed 4–15–93; 8:45 am]

BILLING CODE 6714–01–M

Coastal Barrier Improvement Act; Property Availability; Joe Pool/108, Dallas County, TX

AGENCY: Resolution Trust Corporation.

ACTION: Notice.

SUMMARY: Notice is hereby given that the property known as Joe Pool/108, located in the City of Grand Prairie, in Dallas and Ellis Counties, Texas, is affected by section 10 of the Coastal Barrier Improvement Act of 1990, as specified below.

DATES: Written notices of serious interest to purchase or effect other transfer of the property may be mailed or faxed to the RTC until July 15, 1993.

ADDRESSES: Copies of detailed descriptions of the property, including maps, can be obtained from or are available for inspection by contacting the following person: Mr. Steven Reid, Resolution Trust Corporation, Dallas Field Office, 3500 Maple Avenue, Riverchon Plaza, 18th Floor, Dallas, TX 75219–3935. (214) 443–4738; Fax (214) 443–4825.

SUPPLEMENTARY INFORMATION: The Joe Pool/108 property is located off of Texas Plume Road in Grand Prairie, Texas. The property contains two ponds, has recreational value, and is adjacent to lands managed by the U.S. Army Corps of Engineers as a part of the Joe Pool Lake recreational area. The property is covered property within the meaning of section 10 of the Coastal Barrier Improvement Act of 1990, Public Law 101–591 (12 U.S.C. 1441a–3).

Characteristics of the property include: The Joe Pool/108 property consists of approximately 108.23 acres of undeveloped land. The area immediately surrounding the property is vacant, unimproved land and Joe Pool Lake lies approximately 1,000 feet west of the property. The property contains rolling terrain and two ponds are located near the western edge of the property. Vegetation on the site is principally native grasses and wildflowers with scattered trees.

Property size: Approximately 108.23 acres.

Written notice of serious interest in the purchase or other transfer of the property must be received on or before July 15, 1993 by the Resolution Trust Corporation at the address stated above.

Those entities eligible to submit written notices of serious interest are:

1. Agencies or entities of the Federal government;

2. Agencies or entities of State or local government, and

3. "Qualified organizations" pursuant to section 170(h)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 170(h)(3)).

Written notices of serious interest to purchase or effect other transfer of the property must be submitted by July 15, 1993 to Mr. Steven Reid at the above ADDRESSES and in the following form:

Notice of Serious Interest

RE: Joe Pool/108

Federal Register Publication Date: April 16, 1993

1. Entity name.

2. Declaration of eligibility to submit Notice under critera set forth in Coastal Barrier Improvement Act of 1990, Public Law 101–591, section 10(b)(2), (12 U.S.C. 1441a–3(b)(2)).

3. Brief description of proposed terms of purchase or other offer (e.g., price and method of financing).

4. Declaration by entity that it intends to use the property primarily for wildlife refuge, sanctuary, open space, recreational, historical, cultural, or natural resource conservation purposes.

5. Authorized Representative (Name/Address/Telephone/Fax).

Dated: April 9, 1993.

Resolution Trust Corporation.

William J. Tricarico,

Assistant Secretary.

[FR Doc. 93–8957 Filed 4–15–93; 8:45 am]

BILLING CODE 6714–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–32120; International Series No. 531; File No. SR–CBOE–92–34]

Self-Regulatory Organizations; Filing and Order Granting Accelerated Approval of a Proposed Rule Change by the Chicago Board Options Exchange, Inc., Relating to the Calculation of Exercise Settlement Values for Reduced-Value Financial Times-Stock Exchange 100 Index Options

April 9, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on October 30, 1992, the Chicago Board Options Exchange, Inc. ("CBOE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I and II, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

On September 23, 1991, the Commission approved the CBOE's proposal to list and trade options on a reduced-value Financial Times-Stock Exchange 100 Index ("FT–SE 100" or "Index").[1] Currently, the London Stock Exchange ("LSE") provides the CBOE with minute-by-minute values of the FT–SE 100 and calculates and disseminates the exercise settlement values for the Exchange's reduced-value Index options. The CBOE proposes to amend its rules by adding Exchange Rule 24.9(a)(5), "Other Methods of Determining Exercise Settlement Value," to allow the CBOE to calculate the exercise settlement values for the reduced-value Index options by dividing by ten the value of the Exchange Delivery Settlement Price ("EDSP"), a figure which is calculated by London International Financial Futures and Options Exchange Administration & Management ("LIFFE A&M"), an affiliate of the London International Financial Futures and Options Exchange ("LIFFE"), and used by the LIFFE to settle Index options traded on the LIFFE.[2] The CBOE also proposes to amend Exchange Rule 24.14, "Disclaimers," to provide a liability disclaimer on behalf of LIFFE A&M. Finally, the CBOE proposes to amend Exchange Rule 24.1, "Definitions," to clarify the definitions of "current index value" and "reporting authority." The text of the proposal is available at the Office of the Secretary, CBOE and at the Commission.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

(a) Background. The purpose of the CBOE's proposal is twofold: (1) To amend Exchange Rule 24.9 to clarify the way in which the CBOE will obtain the Index values used to settle the reduced-value Index options listed and traded on the CBOE; and (2) to amend Exchange Rule 24.14 to provide a liability disclaimer on behalf of LIFFE A&M. The CBOE also proposes to amend Exchange Rule 24.1, "Definitions," to provide that, with respect to a particular index, the definition of "current index value" includes "any multiple or fraction of such reported [index] level specified by the Exchange" and to provide that "reporting authority" means the institution or reporting service designated by the CBOE as the official source for calculating the "level of the index from the reported prices of the underlying securities that are the basis of the index and reporting such level."[3]

(b) Method of obtaining exercise settlement values.

(b) Method of obtaining exercise settlement values. The Index options traded on the CBOE are European-style,[4] reduced-value options, with the Index underlying the options calculated to equal one-tenth of the actual level of the Index. The Index Approval Order states that the LSE, which is the licensor of the Index, will provide the CBOE with minute-by-minute values for the Index and will calculate and disseminate the exercise settlement values for the options.

The CBOE has determined that, rather than use the LSE to calculate the exercise settlement values, the EDSPs calculated by LIFFE A&M should serve as the basis for such values. The CBOE believes that the use of the EDSPs generated by LIFFE A&M to determine the exercise settlement values for Exchange-traded Index options will reduce any risk of a discrepancy between the Index values being used in the U.K. to settle FT–SE 100 options and the values being used in the United States by the CBOE to settle FT–SE 100 options. Accordingly, the Exchange has entered into an agreement with LIFFE A&M pursuant to which LIFFE A&M will provide these values to the Exchange. The CBOE will retain the capability to verify the values provided by LIFFE A&M against the minute-by-minute Index values provided to the Exchange by the LSE.

The CBOE proposes to amend Exchange Rule 24.9 to reflect the use of the EDSP in determining the exercise settlement values for the Index options and to reflect that the EDSP is to be reduced by a factor of ten for this purpose. The proposal sates that the

[1] *See* Securities Exchange Act Release No. 29722 (September 23, 1991), 56 FR 49807 (order approving File No. SR–CBOE–91–07) ("Index Approval Order").

[2] The EDSP calculated by LIFFE A&M is denominated in Index points (not in pounds sterling or dollars).

[3] The CBOE states that the proposed changes in the definitions of "current index value" and "reporting authority" are nonsubstantive and are intended to make clear that the reporting authority is responsible only for reporting the value of the underlying index that is used in calculating the current index value, and not for reporting the index value that actually constitutes the current index value. That is, for the Index, the proposed changes make clear that the reporting authority is responsible for reporting the value of the Index, but not current Index values based thereon, which are equal to one-tenth of the underlying Index values.

[4] A European-style option may be exercised only during a specified period of time before the option expires.

EDSP will be determined on the last date preceding expiration for which the Index values are published, and that the last day of trading for Index options traded on the CBOE shall be the trading day on the Exchange immediately preceding the day on which the EDSP used to calculate the current Index value at the expiration of such options is determined.

In addition, the CBOE proposes to add Interpretation .04 to Exchange Rule 24.9 to describe how the EDSP is derived from the values of the Index. Specifically, Interpretation .04 explains that the EDSP used to settle Index options on the LIFFE currently is determined by calculating the average (excluding the three highest and three lowest) of the Index values for each minute in the interval from 10:10 a.m. through 10:30 a.m. London time on the date on which the EDSP is determined. Proposed Interpretation .04 provides that if the LIFFE modifies the method for calculating the EDSP, the CBOE's exercise settlement values will thereafter be based on the EDSP calculated by the LIFFE using the amended method.

Currently, the Index Approval Order states that if the last CBOE trading day for Index options (which would ordinarily be the Thursday prior to expiration) were ever to be the Wednesday prior to expiration, then the exercise settlement value for expiring Index options would be determined based on Thursday's Index values, even if the LSE were open for trading on that Friday. This will no longer be so, since exercise settlement values will be based on EDSP values and the EDSP for an expiration will be based on the Index values from 10:10 a.m. to 10:30 a.m. London time on the last day prior to expiration on which the Index values will be published, *i.e.*, on Friday if the LSE is open for trading.

Finally, the CBOE proposes to add new Interpretation .05 to Exchange Rule 24.9 to make it clear that, if the method of determining the current index value used in settling the exercise of an index option is not described in the CBOE's Rules, the Rules of the Options Clearing Corporation ("OCC") provide that the current index value will be based on the closing prices of the securities underlying the Index on the day of the exercise. Proposed Interpretation .05 is not intended to make any substantive change, but to operate as an aid to a reader of the CBOE's Rules in understanding the relationship of the Exchange's Rules to the OCC's Rules.

(c) Addition of disclaimer of liability on behalf of LIFFE A&M. The CBOE has agreed with LIFFE A&M to place a disclaimer of liability on behalf of LIFFE A&M in the CBOE's rules. The CBOE notes that the disclaimer is similar in concept to the disclaimer on behalf of Standard & Poor's Corporation that is currently in the CBOE's rules and the disclaimer in the Exchange's rules on behalf of Frank Russell Company which was approved recently by the Commission.[5]

(2) *Statutory Basis*

The Exchange believes that the proposal is consistent with section 6(b) of the Act, in general, and further the objectives of section 6(b)(5), in particular, in that it permits the Exchange to use a method for determining exercise settlement values for FT–SE 100 options that has reduced potential for error. The CBOE also believes that the proposal is consistent with the Act in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The CBOE does not believe that the proposed rule change will impose any inappropriate burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

No written comments were either solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has requested that the proposed rule change be given accelerated effectiveness pursuant to Section 19(b)(2) of the Act.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6(b)(5) thereunder.[6] Specifically, the Commission finds that the proposal to allow the CBOE to determine the Index's settlement values by using the EDSPs calculated by LIFFE A&M will contribute to the maintenance of fair and orderly markets by eliminating potential disparities between the settlement values of the Index options traded on the LIFFE and the settlement values of the reduced-value Index options traded on the CBOE. This, in turn, should help to ensure that the reduced-value Index options traded on the CBOE will provide an effective mechanism for hedging investments in the British equity market. The Commission also notes that the CBOE has distributed a circular to its membership describing the change in the settlement method and the implications of the change on the calculation of the settlement value.[7] Further, the Commission believes that it is reasonable, and consistent with the Act, for the proposal to provide that the CBOE will continue to use the EDSP determined by LIFFE A&M even if LIFFE A&M modifies the method it uses to calculate the EDSP because to do so will provide consistency in the calculation of Index settlement values.[8]

The Commission believes that proposed Interpretation .05 will benefit investors by stating explicitly that, unless the CBOE's rules provide otherwise, the Rules of the OCC apply to the calculation of the current index value used to settle index options traded on the Exchange. The Commission believes that this codification of the relationship between the Exchange's rules and the rules of the OCC should benefit market participants by clarifying the Exchange's rules regarding the settlement of index options traded on the Exchange. Similarly, the Commission believes that it is reasonable for the Exchange to modify its definitions of "current index value" and "reporting authority" to reflect the proposal's modification of the method used to calculate the exercise settlement values of CBOE-traded Index options and to make clear that the reporting authority is responsible for reporting the value of the Index, but not the current Index values based thereon.

Finally, the Commission finds that the proposed disclaimer on behalf of LIFFE A&M is similar to disclaimers approved previously by the Commission.[9]

The Commission finds good cause for approving the proposal prior to the thirtieth day after the date of

[5] *See* Securities Exchange Act Release No. 31382 (October 30, 1992) (order approving File No. SR–CBOE–92–02).

[6] 15 U.S.C. 78f(6)(5) (1982).

[7] *See* CBOE Regulatory Circular RG93–07, dated January 13, 1993, and letter from Joanne Moffic-Silver, Associate General Counsel, CBOE, to Yvonne Fraticelli, Staff Attorney, Options Branch, Division of Market Regulation, Commission, dated March 3, 1993.

[8] The Commission, however, requests that it be notified of any change in determining the method for calculating the EDSP as soon as possible and that the change be filed with it pursuant to section 19(b) of the Act. In addition, any change in the methodology should be disseminated to members before its implementation.

[9] *See* Securities Exchange Act Release No. 31382, *supra* note 5.

publication of notice of filing thereof in the **Federal Register** in order to allow the CBOE to calculate the settlement values of the Index options according to the revised procedures. In this regard, in light of the fact that the first expiration of Exchange-traded Index options occurred in November 1992, the Commission believes accelerated approval of the proposal will avoid a situation where investors will become acclimated to one settlement method for several expirations and then the settlement method will be changed. The Commission also finds that Interpretation .05 codifies the current practice of the CBOE in connection with the settlement of index options traded on the Exchange and does not raise new regulatory issues. Similarly, the Commission finds that the modifications of the definitions of "current index value" and "reporting authority" are technical in nature and do not raise new issues. Finally, the Commission notes that the disclaimer on behalf of LIFFE A&M is similar to disclaimers approved previously by the Commission. Therefore, the Commission believes it is consistent with sections 6(b)(5) and 19(b)(2) of the Act to approve the proposed rule change on an accelerated basis.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying at the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by May 7, 1993.

It is therefore ordered, Pursuant to section 19(b)(2) of the Act,[10] that the proposed rule change (SR–CBOE–92–34) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[11]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–8908 Filed 4–15–93; 8:45 am]

BILLING CODE 8010-01-M

[10] 15 U.S.C 78s(b)(2) (1988).

[11] 17 CFR 200.30–3(a)(12) (1991).

[Release No. 35–25789]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

April 9, 1993.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by May 3, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

UNITIL Corporation, et al. (70–8074)

UNITIL Corporation ("UNITIL"), a registered holding company, and its service company subsidiary, UNITIL Service Corp. ("Service Corp."), both at 216 Epping Road, Exeter, New Hampshire 03833, have filed an application-declaration under sections 6(a), 7, 9(a), 10, 12(b) and 13(b) of the Act and Rules 45, 87, 90 and 91 thereunder, seeking authorization for the proposed transactions described herein through December 31, 1997.

UNITIL proposes to create and provide financing for a new nonutility subsidiary company, UNITIL Resources, Inc. ("Resources"). UNITIL proposes to acquire all 100 shares of Resources' common stock, par value $1 per share, for a total purchase price of $10,000 and to invest up to $190,000 through the acquisition of additional stock, capital contributions, open account advances or subordinated debt. The aggregate amount of all investments, including the purchase of common stock, by UNITIL in Resources shall not exceed $200,000. Any such open account advances or subordinated loans will have a term of ten years or less and will bear interest at a rate based on UNITIL's cost of funds in effect on the date of issue, but in no event in excess of the prime rate charged by UNITIL's lead bank, currently the Bank of Boston.

In addition, Resources may, from time to time, need UNITIL to indemnify third parties, to guarantee performance of its obligations or payment of its debts and to act as surety for its activities. Such indemnities and guarantees will not exceed $300,000 in the aggregate at any one time.

Resources proposes to engage in the business of providing consulting and other services on energy related matters to nonaffiliates for profit. The consulting and other services may include: (1) Serving as power brokering agent for electric power owned by a client;[1] (2) serving as purchasing agent for a utility or other bulk power purchaser client; (3) making regulatory assessments; (4) performing administrative, management and billing functions; (5) producing studies and reports; (6) holding meetings with technical staff to assess problems and potential solutions; (7) conducting seminars; (8) developing and proposing programs for implementation by the customer; and (9) providing other similar consulting, financial and administrative services. The consulting and other services shall not include operation or maintenance of any facilities, electric or otherwise, nor investment, directly or indirectly, in the facilities or operations of a third party, whether through a joint venture, partnership, or debt or equity financing. Furthermore, in providing power brokering and purchasing services,

[1] The application-declaration states that UNITIL has entered into a marketing agent agreement with Great Bay Power Corporation ("Great Bay"), the successor company to EUA Power Corporation, for the sale of electricity produced by Great Bay's 12.1324% interest in the Seabrook Nuclear Power Station. UNITIL will assign the marketing agent agreement to Resources after Commission approval sought herein is granted.

Resources will not purchase and resell any electric power.

Initially, Resources will not have its own employees. Resources will contract with Service Corp. for the performance of any consulting or other assignments which it obtains and such work will be performed by employees of Service Corp. Depending on the nature of the project, Service Corp. may also assign employees from various other UNITIL system companies; however, no employees will be assigned to a Resources project if such assignment will interfere with the normal operation of the UNITIL system utility companies. In addition, accounting, credit, financial, management, technical and clerical support will be provided by Service Corp. to Resources.

Entergy Corporation (70–8149)

Entergy Corporation ("Entergy"), 225 Baronne Street, New Orleans, Louisiana 70112, a registered holding company, has filed a declaration under sections 6(a), 7, 32 and 33 of the Act.

Entergy proposes to enter into arrangements with one or more banks that would permit it to effect borrowings and reborrowings, from time to time no later than May 31, 1996, of not more than $300 million at any one time outstanding by issuing to the participating banks ("Banks") its unsecured promissory notes payable no later than May 31, 1996 ("Notes"). The proposed borrowing arrangements will be contained in a credit agreement among Entergy and the Banks.

Under the proposed arrangements, each borrowing would bear interest from the date thereof on the unpaid principal amount thereof at a rate per annum selected by Entergy from a number of specified interest rate options. Such interest rate options will include some or all of the following: (i) The prime commercial loan rate of a specified Bank (or an average of such rates of some or all of the Banks) ("Prime Rate") from time to time in effect; (ii) the sum of: (A) Specified offered rates for certificates of deposit of a specified Bank (or an average of such rates of some or all of the Banks) for amounts equivalent to such borrowing and for selected interest periods, appropriately adjusted for the cost of reserves and F.D.I.C. insurance and (B) a margin not in excess of 1% per annum ("CD Rate"); (iii) the sum of: (A) Specified rates offered for U.S. dollar deposits by or to a specified Bank (or an average of such rates of some or all of the Banks) in the interbank eurodollar market for amounts equivalent to such borrowing and for selected interest periods, appropriately adjusted for the cost of reserves and (B) a margin not in excess of 1% per annum ("LIBOR Rate"); or (iv) a rate negotiated at the time of borrowing with one or more Banks, which would not in any event exceed a maximum rate of the Prime Rate plus 2% per annum, appropriately adjusted for the cost of bidding or negotiation ("Competitive Advance Rate").

Entergy states that it may agree to pay each Bank a facility fee for the period from the commencement of the borrowing arrangements to and including May 31, 1996 (or any earlier date of termination of the Commitments) computed at a rate not in excess of ¼ of 1% per annum of the total Commitments in effect during the period for which payment is made. Entergy states that it may also agree to pay to the agent Bank (if any) an agent fee for the period from the commencement of the borrowing arrangements to and including May 31, 1996 (or any earlier date of termination of the Commitments) not in excess of $200,000 per annum. Entergy further asserts that it may also agree to pay to the Banks an up-front fee not in excess of 1% of the total commitments.

Entergy states that it intends to repay the proposed borrowings out of internally generated funds and/or the proceeds of such forms of financing as are hereafter approved by the Commission and/or other funds that become available to Entergy.

Entergy intends to use the proceeds from the sale of its Notes for: (i) The acquisition of shares of Entergy's outstanding common stock pursuant to outstanding Commission authorization; and (ii) subject to future Commission authorization, if necessary, for investments in domestic utility projects that are exempt wholesale generators and in foreign utility projects subject to sections 32 and 33 of the Act, respectively and, to a lesser extent, related non-utility businesses. Entergy undertakes that it will comply with any rules that are adopted by the Commission under sections 32 and 33 of the Act relating to investments in exempt wholesale generators and foreign utility companies.

Public Service Company of Oklahoma (70–8177)

Public Service Company of Oklahoma ("PSC–OK"), 212 East Sixth Street, Tulsa, Oklahoma 74119, an electric public-utlity subsidiary company of Central and South West Corporation, a registered holding company, has filed a declaration under section 12(d) of the Act and Rule 44 thereunder.

PSC–OK owns and maintains, as a part of its transmission and distribution system, certain transformation facilities ("Facilities") which are located on the premises of a PSC–OK commercial customer and nonassociate company, Ruffin Properties ("Buyer"). The Facilities consist of five three phase, 13.2 kv/480–277 volt step-down transformers and associated equipment and facilities.

PSC–OK proposes to sell, and the Buyer desires to purchase, the Facilities for a cash price of $221,517, which is based on depreciated replacement value. The original cost of the Facilities was $188,384. As of February 28, 1993, the book value of the Facilities, net of depreciation, was $132,169.

The purchase price of the Facilities was reached through arms-length negotiations. The Buyer is the only customer serviced by the Facilities. Furthermore, the Facilities are not adaptable at that location for use in serving any other customer, and it would not be commercially feasible for PSC–OK to sell individual parts of the Facilities.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–8962 Filed 4–15–93; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 35–25788]

Filings Under the Public Utility Holding Company Act of 1935 ("Act")

April 9, 1993.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated thereunder. All interested persons are referred to the application(s) and/or declaration(s) for complete statements of the proposed transaction(s) summarized below. The application(s) and/or declaration(s) and any amendments thereto is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by May 3, 1993 to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarant(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by

certificate) should be filed with the request. Any request for hearing shall identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After said date, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

The Southern Company (70–8181)

Proposal To Increase Number of Shares of Authorized Common Stock; Order Authorizing Solicitation of Proxies

The Southern Company ("Southern"), 64 Perimeter Center East, Atlanta, Georgia 30346, a registered holding company, has filed a declaration under sections 6(a), 7 and 12(e) of the Act and Rule 62 thereunder.

Southern proposes to amend ("Amendment") the fourth Article of its Certificate of Incorporation in order to increase, from 500 million to 1 billion, the total number of shares of common stock, par value $5.00 per share, that Southern shall have authority to issue.

Southern states that it considers such increase in the amount of authorized but unissued common stock necessary to: provide flexibility for general corporate requirements (including investments by stockholders under Southern's Dividend Reinvestment and Stock Purchase Plan and by or on behalf of employees under its Employee Stock Ownership Plan and Employee Savings Plan); effect a stock split by delivering a pro rated number of shares of common stock to all holders of record, should the board of directors deem it advisable in the future; and, provide additional capital of a currently undetermined nature requiring the issuance of additional common stock. Such future transactions may include possible future stock splits, financings and acquisitions and measures relating to takeover initiatives directed at Southern or its stockholders. If the proposed Amendment is adopted, Southern would be permitted to issue the authorized shares without further stockholder approval, except to the extent otherwise required by law, by a securities exchange on which the common stock is listed or by the Certificate of Incorporation. Future issuances of common stock by Southern will continue to be subject to the approval of the Commission under the Act.

The proposed Amendment has been proposed and declared advisable by the Board of Directors of Southern and its adoption requires the favorable vote of the holders of a majority of the outstanding shares of common stock of Southern.

Southern proposes to submit the Amendment for consideration and action by its stockholders at the annual meeting to be held on May 26, 1993, and in connection therewith, to solicit proxies from its stockholders. Consequently, Southern requests that the effectiveness of its declaration with respect to such solicitation of proxies be permitted to become effective as provided in Rule 62(d).

It appearing to the Commission that Southern's declaration regarding the proposed solicitation of proxies should be permitted to become effective forthwith, pursuant to Rule 62:

It is ordered, That the declaration regarding the proposed solicitation of proxies be, and it hereby is, permitted to become effective forthwith, pursuant to Rule 62 and subject to the terms and conditions prescribed in Rule 24 under the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 93–8963 Filed 4–15–93; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2638]

Oregon; Declaration of Disaster Loan Area

Clackamas, Marion, and Yamhill Counties and the contiguous counties of Hood River, Jefferson, Linn, Multnomah, Polk, Tillamook, Wasco, and Washington in the State of Oregon constitute a disaster area as a result of damages caused by an earthquake which occurred on March 25, 1993. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on June 7, 1993 and for economic injury until the close of business on January 10, 1994 at the address listed below: U.S. Small Business Administration, Disaster Area 4 Office, P.O. Box 13795, Sacramento, CA 95853–4795, or other locally announced locations.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000
Businesses With Credit Available Elsewhere	8.000
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) With Credit Available Elsewhere	7.625
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 263802 and for economic injury the number is 788500.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: April 8, 1993.

Dayton J. Watkins,

Acting Administrator.

[FR Doc. 93–8950 Filed 4–15–93; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Order 93–4–26; Docket 48514]

Application of Promech, Inc. for Certificate Authority Under Subpart Q

AGENCY: Department of Transportation.

ACTION: Notice of order to show cause.

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Promech, Inc., fit, willing, and able and award it a certificate of public convenience and necessity to engage in interstate and overseas scheduled air transportation.

DATES: Persons wishing to file objections should do so no later than April 27, 1993.

ADDRESSES: Objections and answers to objections should be filed in Docket 48514 and addressed to the Documentary Services Division (C–55, room 4107), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590 and should be served upon the parties listed in attachment A to the order.

FOR FURTHER INFORMATION CONTACT:

Mrs. Kathy Lusby Cooperstein, Air Carrier Fitness Division (P–56, room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–2337.

Dated: April 9, 1993.

Robert S. Goldner,

Special Counsel.

[FR Doc. 93–8874 Filed 4–15–93; 8:45 am]

BILLING CODE 4910–62–M

Research and Special Programs Administration

Office of Hazardous Materials Safety; Applications for Exemptions

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applicants for exemptions.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Transportation has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before May 17, 1993.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Dockets Unit, Room 8426, Nassif Building, 400 7th Street, SW., Washington, DC.

NEW EXEMPTIONS

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
10982–N	Consolidated Papers, Inc., Wisconsin Rapids, WI.	49 CFR 174.67(i)+(j)	To authorize chlorine filled tank cars to remain connected during unloading without the physical presence of an unloader. (Mode 2)
10983–N	U.S. Reduction Co., Munster, IN.	49 CFR 174.67(i)+(j), 177.834(i)(3).	To authorize chlorine filled tank cars and cargo tanks to remain connected during unloading without the physical presence of an unloader. (Modes 1, 2)
10984–N	Airco Electronic Gases, Riverton, NJ.	49 CFR 173.304	To authorize the use of DOT Specification 5A/UN1A1 drum for the shipment of dichlorosilane classed as Division 2.3. (Modes 1, 3)
10985–N	Georgia-Pacific Corporation, Bellingham, WA.	49 CFR 174.67(i)+(j)	To authorize chlorine filled tank cars to remain connected without the physical presence of an unloader. (Mode 2)
10986–N	Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 173.302(c)(2)(3)+(4), 173.34(e)(1)(3)(4)+(6).	To authorize ultrasonic retesting of DOT-Specification 3A cylinders used for shipment of liquefied and non-liquefied compressed gases, and mixtures of two or more gases classed as Division 2.1, 2.2 and 2.3 material. (Mode 1)
10987–N	Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 173.163, 173.192(a), 173.302(a)(1), 173.304(a)(2), 173.34(d)+(e).	To authorize the use of non-DOT specification salvage cylinders for shipment of certain hazardous materials which are authorized to be shipped in DOT-Specification cylinders. (Mode 1)
10988–N	Ensign-Bickford Company, Simsbury, CT.	49 CFR 173.62	To authorize the shipment of articles, explosives, n.o.s., Division 1.4D, in interplant shipments on public highway in specifically designed containers (shock tubes). (Mode 1)
10989–N	Eagle-Picher Ind, Inc., Joplin, MO.	49 CFR 173.159(g)(2)	To authorize the transport of electrolyte acid, or battery fluid alkaline, Class 8, included with storage batteries and filing kits overpacked in sealed steel drums when shipments are made by, for or to the Department of Defense. (Mode 1)
10990–N	Air Transport Association of America, Washington, DC.	49 CFR 173.34(e)	To authorize an alternative maintenance program for DOT-Specification 4DA and 4DS hermetically sealed cylinders charged with bromotrifluoromethane, compressed, Division 2.2 used as components on aircraft fire suppression systems. (Modes 1, 4, 5)
10991–N	3M Company, St. Paul, MN	49 CFR 173.24(c), 173.314	To authorize the transport of certain non-corrosive, liquefied gas classed as Division 2.2 in non-DOT specification tank, similar to a multi-unit tank car unit, with a water capacity of approximately 1800 pounds. (Modes 1, 2, 3)
10993–N	Columbia Helicopters, Inc., Portland, OR.	49 CFR 172.101(9)(b), 173.241–243.	To authorize the transportation of bulk quantities of flammable liquids in non-DOT specification seal drums (rollagons) up to 500 gallons capacity. (Mode 4)
10994–N	ICI Explosives USA, Inc., Dallas, TX.	49 CFR 172.101 Cols 7+8, 173.24(c), 173.54(e), 177.821, 177.834(1), 177.835(b), 177.835(k), 177.835(m).	To authorize the transportation of liquid explosives, substances, explosives, n.o.s. classed as Division 1.1C, 1.1D or 1.3C in non-DOT specification containers. (Modes 1, 3)
10995–N	James River Paper Company, Camas, WA.	49 CFR 174.67(i)+(j)	To authorize chlorine filled tank cars to remain connected during unloading without the physical presence of an unloader. (Mode 1)
10996–N	AeroTech, Inc. & Industrial Solid Propulsion, Inc., Las Vegas, NV.	49 CFR 173 Subpart C	To authorize the transportation of limited quantities of composite propellant rocket motors as Class 1.4 in specially designed packaging. (Modes 1, 2)

NEW EXEMPTIONS—Continued

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
10997–N	HR Textron, Inc., Pacoima, CA.	49 CFR 173.302(a), 175.3	To authorize the manufacture, mark and sell of non-DOT specification reusable cylinders having a 277 cubic inches maximum water capacity constructed of titanium alloy and built to requirements of DOT-specification 3HT for use in transportation of nitrogen or mixtures classed as Division 2.2. (Modes 1, 2, 4, 5)
10999–N	OEA, Inc., Denver, CO	49 CFR 173.34(d)	To authorize DOT Specification cylinders containing a compressed gas used within an automotive airbag inflator system to be exempt from the burst test requirement of the CGA pamphlet S–1.1 referenced in section 173.34(d). (Modes 1, 2, 3, 4, 5)

This notice of receipt of applications for new exemptions is published in accordance with part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on April 9, 1993.

Suzanne Hedgepeth,

Chief, Exemptions Branch, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 93–8964 Filed 4–15–93; 8:45 am]

BILLING CODE 4910-60-M

Office of Hazardous Materials Safety; Notice of Applications for Modification of Exemptions or Applications To Become a Party to an Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for modification of exemptions or applications to become a party to an exemption.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR Part 107, Subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier Federal Register publications, they are not repeated here. Requests for modifications of exemptions (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix "X" denote a party to request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before May 3, 1993.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Dockets Unit, room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

Application No.	Applicant	Renewal of exemption
4453–X	Mining Services International (MSI), Salt Lake City, UT (See Footnote 1).	4453
6563–X	Mada Medical Products, Inc., Carlstadt, NJ (See Footnote 2).	6563
7607–X	The Foxboro Co., East Bridgewater, MA (See Footnote 3).	7607
9645–X	Bonar Plastics Ltd., Lindsay, Ontario, CN (See Footnote 4).	9645
10097–X ...	Hercules Aerospace Co., Magna, UT (See Footnote 5).	10097
10692–X ...	Technical Manufactured Products, Jasper, GA (See Footnote 6).	10692

[1] To modify exemption to provide for rail as an additional mode of transportation for transporting various classes of hazardous materials in non-DOT specification bulk, hopper-type tanks.

[2] To renew exemption to authorize the continued use of cylinders, constructed with welded tubing and longitudinal seams, for the use of materials classed as Division 2.2, with no new construction authorized.

[3] To modify exemption to provide for additional non-DOT specification cylinder for use in shipment of hydrogen, classed in Division 2.1, on passenger-carrying aircraft.

[4] To modify exemption to provide for minor change to the portable tanks used for transportation of various classes of hazardous materials.

[5] To modify exemption to provide for the transportation of an additional assembly consisting of a Pegasus XL Second and Third stage rocket motor.

[6] To provide for changes in the design configuration and provide for an additional model of non-DOT specification cylinder for transporting liquefied petroleum gas, classed as Division 2.1.

Application No.	Applicant	Parties to exemption
4453–P	Senex Explosive, Inc.; Cuddy, PA.	4453
4850–P	Accurate Arms Company, Inc., McEwen, TN.	4850
6626–P	Haun Welding Supply, Inc., Syracuse, NY.	6526
6691–P	Geneva Welding Supply, Inc., Geneva, NY.	6691
7060–P	Aviserv, Inc., Columbus, OH.	7060
8214–P	Allied Signal Automotive Safety Restraint Systems, Sterling Heights, MI.	8214
8451–P	Takata Moses Lake, Inc., Moses Lake, WA.	8451
8451–P	Magnavox Electronic Systems Co., Fort Wayne, IN.	8451
8451–P	HITECH, Inc., East Camden, AR.	8451
8582–P	Columbia Colt Terminal, Columbia, MO.	8582
8723–P	Senex Explosives, Inc., Cuddy, PA.	8723
8723–P	Dyno New England, Inc., Middlefield, CT.	8723
8966–P	Aqua Tri, Irvine, CA ...	8966
9198–P	Idaho Department of Lands, Coeur d'Alene, ID.	9198
9222–P	LWD Trucking, Inc., Calvert City, KY.	9222

Application No.	Applicant	Parties to exemption
9262–P	High Energy International, Fort Worth, TX.	9262
9275–P	Florasynth Inc., Teterboro, NJ.	9275
9549–P	High Energy International, Fort Worth, TX.	9549
9723–P	Security Environmental Systems, Inc., Los Angeles, CA.	9723
9723–P	Mr. Frank, Inc., Matteson, IL.	9723
9723–P	Clean Harbors of Natick, Inc., Natick, MA.	9723
9723–P	Rollins CHEMPAK Inc., Wilmington, DE.	9723
10441–P ...	Security Environmental System, Inc., Los Angeles, CA.	10441
10683–P ...	Witco Corp., New York, NY.	10683
10904–P ...	S.C. Johnson & Son, Inc., Racine, WI (See Footnote 1).	10904
10917–P ...	Eagle-Picher Industries, Inc., Joplin, MO.	10917
10917–P ...	AEG Corp., Basking Ridge, NJ.	10917
10917–P ...	Silent Power, Inc., Wayne, PA.	10917
10917–P ...	ABB Advanced Battery Systems Inc., Mississauga, Ontario, CN.	10917

[1] To authorize party status and provide for relief of communication requirements.

This notice of receipt of applications for renewal of exemptions and for party to an exemption is published in accordance with Part 107 of the Hazardous Materials Transportations Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on April 9, 1993.

J. Suzanne Hedgepeth,

Chief, Exemptions Branch, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 93–8965 Filed 4–15–93; 8:45 am]

BILLING CODE 4910-60-M

DEPARTMENT OF THE TREASURY

Public Information Collection Requirements Submitted to OMB for Review

Dated: April 12, 1993.

The Department of Treasury has submitted the following public information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96–511. Copies of the submission(s) may be obtained by calling the Treasury Bureau Clearance Officer listed. Comments regarding this information collection should be addressed to the OMB reviewer listed and to the Treasury Department Clearance Officer, Department of the Treasury, Room 3171 Treasury Annex, 1500 Pennsylvania Avenue, NW., Washington, DC 20220.

U.S. Savings Bonds Division

OMB Number: New
Form Number: None
Type of Review: New collection
Title: U.S. Savings Bonds National Market Research Project Distribution System Study
Description: This study is a follow up to previous Market Research study of consumer awareness, extent of ownership, and savings habits demographics. This new study will examine the distribution system and methods of preparation and delivery of Bonds to purchasers.
Respondents: Businesses or other for-profit
Estimated Number of Respondents: 1,200
Estimated Burden Hours Per Respondent: 30 minutes
Frequency of Response: Other (one time)
Estimated Total Reporting Burden: 600 hours
Clearance Officer: Richard J. Schneebeli, (202) 377–7704, U.S. Savings Bonds Division, Room 8035, 800 K Street, NW., Washington, DC 20226.
OMB Reviewer: Milo Sunderhauf, (202) 395–6880, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, DC 20503.

Lois K. Holland,

Departmental Reports Management Officer.

[FR Doc. 93–8954 Filed 4–15–93; 8:45 am]

BILLING CODE 4830-01-M

[Treasury Directive Number: 15–62]

Authority of the Office of Foreign Assets Control

Dated: April 7, 1993.

1. *Delegation.* By virtue of the authority vested in the Secretary of the Treasury, including the authority vested by 31 U.S.C. 321(b), and pursuant to the authority delegated to the Assistant Secretary (Enforcement) by Treasury Order 105–03, the Director, Office of Foreign Assets Control, is hereby delegated all powers and authorities delegated to the Secretary of the Treasury by Executive Orders relating to the resolution of claims of United States nationals against Iran and the beginning of the process of normalization of relations between the United States and Iran.

2. *Cancellation.* Treasury Directive 15–62, "Authority of the Office of Foreign Assets Control," dated September 29, 1986, is superseded.

3. *Office of Primary Interest.* Office of the Assistant Secretary (Enforcement).

John P. Simpson,

Acting Assistant Secretary (Enforcement).

[FR Doc. 93–8960 Filed 4–15–93; 8:45 am]

BILLING CODE 4810-25-M

[Cost Center 4810–25; Treasury Directive Number: 15–22]

Reimbursable Services of Customs in the Virgin Islands

Dated: April 7, 1993.

1. *Action.* This directive authorizes the following.

a. The rates of extra compensation for services performed in connection with the administration of the customs laws of the United States shall apply to officers and employees appointed for the administration of the customs laws in the Virgin Islands of the United States.

b. Payments to officers and employees in the Virgin Islands for extra compensation shall be made from the Virgin Islands Trust Fund. Collections from parties in interest for extra compensation will be made by the Government of the Virgin Islands under authority of its local laws.

c. The application of the rates to Virgin Islands customs officers and employees will be subject to the regulations, decisions, directions for assignment and control of personnel and the accounting procedures that are applicable to customs officers other than those in the Virgin Islands.

2. *Cancellation.* Treasury Directive 15–22, "Reimbursable Services Of Customs In The Virgin Islands," dated July 30, 1986, is superseded.

3. *Authorities.*

a. 48 U.S.C. 1406h.

b. 19 U.S.C. 267.

4. *Office of Primary Interest.* Office of the Assistant Secretary (Enforcement)

John P. Simpson,

Acting Assistant Secretary (Enforcement)

[FR Doc. 93–8961 Filed 4–15–93; 8:45 am]

BILLING CODE 4810-25-M

DEPARTMENT OF VETERANS AFFAIRS

Special Medical Advisory Group; Availability of Annual Report

Under section 10(d) of Public Law 92–463 (Federal Advisory Committee Act) notice is hereby given that the Annual Report of the Department of Veterans Affairs' Special Medical Advisory Group for Fiscal Year 1992 has been issued. The report summarizes activities of the Group on matters relative to the care and treatment of disabled veterans and other matters pertinent to the Department of Veterans Affairs' Veterans Health Administration. It is available for public inspection at two locations:

Federal Documents Section, Exchange and Gift Division, LM 632, Library of Congress, Washington, DC 20540

and

Department of Veterans Affairs, Office of the Under Secretary for Health, Techworld Room 710, 801 I Street, NW., Washington, DC 20001.

Dated: March 5, 1993.

Heyward Bannister,

Committee Management Officer.

[FR Doc. 93–8904 Filed 4–15–93; 8:45 am]

BILLING CODE 8320–01–M

Sunshine Act Meetings

Federal Register
Vol. 58, No. 72
Friday, April 16, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 2:00 p.m. on Tuesday, April 20, 1993, to consider the following matters:

Summary Agenda

No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Reports of actions approved by the standing committees of the Corporation and by officers of the Corporation pursuant to authority delegated by the Board of Directors.

Memorandum and resolution re: Extension of public comment period on the conducting of a Pilot Reinsurance Program.

Discussion Agenda

Memorandum and resolution re: Petitions to repeal portions of Part 362 of the Corporation's rules and regulations, entitled "Activities and Investments of Insured State Banks," and to reopen the rulemaking for further public comment.

Memorandum and resolution re: Proposed amendments to Part 303 of the Corporation's rules and regulations, entitled "Applications, Requests, Submittals, Delegations of Authority, and Notices of Acquisition of Control," which would (1) conform the definitions of "significant risk" and "equity security" to the definitions of those terms found in Part 362 of the Corporation's rules and regulations, entitled "Activities and Investments of Insured State Banks," (2) allow insured state savings associations to conduct activities and make investments without the Corporation's prior approval provided that the activities and/or investments were found to be permissible for federal savings associations under an order or a written interpretation issued by the Office of Thrift Supervision, and (3) place insured state savings associations on a par with the treatment accorded insured state banks under the Corporation's rules and regulations.

Memorandum and resolution re: Proposed amendments to Part 325 of the Corporation's rules and regulations, entitled "Capital Maintenance," which would establish a limitation on the amount of certain deferred tax assets that may be included (that is, not deducted from) in the Tier 1 capital calculation for risk-based and leverage capital purposes.

Memorandum and resolution re: Final amendments to the Corporation's rules and regulations in the form of a new Part 363 regarding independent annual audits and reporting requirements.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call (202) 898–6745 (Voice); (202) 898–3509 (TTY), to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898–6757.

Dated: April 13, 1993.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 93–9038 Filed 4–13–93; 4:41 pm]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 2:30 p.m. on Tuesday, April 20, 1993, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors, pursuant to sections 552b (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of Title 5, United States Code, to consider the following matters:

Summary Agenda

No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Matters relating to the Corporation's corporate activities.

Recommendations with respect to the initiation, termination, or conduct of administrative enforcement proceedings (cease-and-desist proceedings, termination-of-insurance proceedings, suspension or removal proceedings, or assessment of civil money penalties) against certain insured depository institutions or officers, directors, employees, agents or other persons participating in the conduct of the affairs thereof.

Names of persons and names and locations of depository institutions authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(6), (c)(8), and (c)(9)(A)(ii) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(6), (c)(8), and (c)(9)(A)(ii)).

Note: Some matters falling within this category may be placed on the discussion agenda without further public notice if it becomes likely that substantive discussion of those matters will occur at the meeting.

Discussion Agenda

Matters relating to the possible closing of certain insured depository institutions:

Names and locations of depository institutions authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

Personnel actions regarding appointments, promotions, administrative pay increases, reassignments, retirements, separations, removals, etc.:

Names of employees authorized to be exempt from disclosure pursuant to the provisions of subsections (c)(2) and (c)(6) of the "Government in the Sunshine Act" (5 U.S.C. 552b (c)(2) and (c)(6)).

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898–6757.

Dated: April 13, 1993.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 93–9039 Filed 4–13–93; 4:41 pm]

BILLING CODE 6714-01-M

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b(e)(2)), notice is hereby given that at 10:09 a.m. on Tuesday, April 13, 1993, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider the following:

Matters relating to the probable failure of a certain insured bank.

Matters relating to the Corporation's corporate activities.

Matters relating to assistance agreements with insured institutions.

Matters relating to the Corporation's resolution activities.

In calling the meeting, the Board determined, on motion of Director Jonathan L. Fiechter (Acting Director, Office of Thrift Supervision), seconded by Director Eugene A. Ludwig (Comptroller of the Currency), concurred in by Acting Chairman Andrew C. Hove, Jr., that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550—17th Street, NW., Washington, DC.

Dated: April 13, 1993.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Deputy Executive Secretary.

[FR Doc. 93–9040 Filed 4–13–93; 4:41 pm]

BILLING CODE 6714–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: Approximately 11:00 a.m., Wednesday, April 21, 1993, following a recess at the conclusion of the open meeting.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets NW., Washington, DC 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Proposed acquisition of communications equipment within the Federal Reserve System.
2. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
3. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204 You may call (202) 452–3207, beginning at approximately 5 p.m. two business days before this meeting, for a recorded announcement of bank and bank holding company applications scheduled for the meeting.

Dated: April 14, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–9070 Filed 4–14–93; 1:46 pm]

BILLING CODE 6210–01–M

BOARD OF GOVERNORS OF THE FEDERAL RESERVE SYSTEM

TIME AND DATE: 10:00 a.m., Wednesday, April 21, 1993.

PLACE: Marriner S. Eccles Federal Reserve Board Building, C Street entrance between 20th and 21st Streets, NW., Washington, DC 20551.

STATUS: Open.

MATTERS TO BE CONSIDERED:

Summary Agenda

Because of its routine nature, no substantive discussion of the following item is anticipated. This matter will be voted on without discussion unless a member of the Board requests that the item be moved to the discussion agenda.

1. Proposed amendments to Regulation O (Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks) to implement amendments contained in The Housing and Community Development Act of 1992. (Proposed earlier for public comment; Docket No. R–0785)

Discussion Agenda

1. Publication for comment on extending or eliminating a provision in Regulation O (Loans to Executive Officers, Directors, and Principal Shareholders of Member Banks) that provides an exception for smaller banks to the general limit on aggregate lending to insiders.
2. Proposal to issue a notice of proposed rulemaking for Section 132 of the Federal Deposit Insurance Corporation Improvement Act of 1991 regarding safety and soundness standards. (Proposed earlier for public comment; Docket No. R–0766)
3. Any items carried forward from a previously announced meeting.

Note: This meeting will be recorded for the benefit of those unable to attend. Cassettes will be available for listening in the Board's Freedom of Information Office, and copies may be ordered for $5 per cassette by calling (202) 452–3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, DC 20551.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: April 14, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93–9071 Filed 4–14–93; 1:46 pm]

BILLING CODE 6210–01–M

NATIONAL SCIENCE FOUNDATION

Special Emphasis Panel in Atmospheric Sciences; Notice of Meeting

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to review and evaluate proposals and provide advice and recommendations as part of the selection process for awards. Because the proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals, the meetings are closed to the public. These matters are within exemptions (4) and (6) of 5 U.S.C., 552b(c), Government in the Sunshine Act.

Name: Special Emphasis Panel in Atmospheric Sciences.

Date: May 6 and 7, 1993.

Time: 9:00 a.m. to 5:00 p.m. on May 6; 9:00 a.m. to 11:30 a.m. on May 7.

Place: UNIDATA Program Center Office, 3300 Mitchell Lane, Boulder, Colorado.

Type of Meeting: Closed.

Agenda: Review and evaluation of proposals requesting grants to purchase computer and related equipment to be used in support of UNIDATA activities at the proposers respective institution.

Contact: Dr. Clifford A. Jacobs, Facilities Coordinator, Division of Atmospheric Sciences, National Science Foundation, Washington, DC (202) 357–9889.

Dated: April 14, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93–9043 Filed 4–14–93; 10:04 am]

BILLING CODE 7555–01–M

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

TIME AND DATE: 10:00 a.m., Tuesday, April 20, 1993.

PLACE: Room 600, 1730 K Street, NW., Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. *BethEnergy Mines, Inc.*, Docket No. PENN 89–277–R etc. (Issues include whether the judge erred in vacating two citations charging violations of a notice to provide safeguards that had been issued to BethEnergy pursuant to 30 CFR 75.1403.)
2. *S & H Mining, Inc.*, Docket No. SE 91–32. (Issues include whether the judge erred in concluding that S & H's violation of 30 CFR 75.902 was of a significant and substantial nature and was caused by its unwarrantable failure to comply with the safety standard.)

Any person attending this meeting who requires special accessibility features and/or auxiliary aids, such as sign language interpreters, must inform the Commission in advance of those needs. Subject to 29 CFR 2706.150(a)(3) and 2706.160(e).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen (202) 653–5629/(202) 708–

9300 for TDD Relay/ 1–800–877–8339 for toll free.

Jean H. Ellen,

Agenda Clerk.

[FR Doc. 93–9118 Filed 4–14–93; 3:54 pm]

BILLING CODE 6735–01–M

Corrections

Federal Register
Vol. 58, No. 72
Friday, April 16, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

International Trade Administration

[C-428-817]

Preliminary Affirmative Countervailing Duty Determinations and Alignment of Final Countervailing Duty Determinations With Final Antidumping Duty Determinations: Certain Steel Products From Germany

Correction

In notice document 92-29502 beginning on page 57772 in the issue of Monday, December 7, 1992, make the following correction:

On page 57778, in the 3rd column, in the 1st full paragraph, in the 17th line, "0.44" should read "0.14".

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 141

[Docket No. RM93-10-000]

New Reporting Requirement Under the Federal Power Act and Changes to Form No. FERC-714; Proposed Rulemaking

Correction

In proposed rule document 93-7825 beginning on page 17544 in the issue of Monday, April 5, 1993, on page 17550, in the first column, in the first full paragraph, in the fifth line, "April 19, 1993." should read "May 20, 1993."

BILLING CODE 1505-01-D

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. ER93-471-000, et al.]

Cleveland Electric Illuminating Company, et al.; Electric Rate, Small Power Production, and Interlocking Directorate Filings

Correction

In notice document 93-7823 beginning on page 17580 in the issue of Monday, April 5, 1993, on page 17582, in the first column, under 10. Southwestern Power Administration, "[Docket No. ER93-4081-000]" should read "[Docket No. EF93-4081-000]".

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 1 and 101

[Docket No. 90N-0165]
RIN 0905-AD08

Food Labeling; Serving Sizes; Technical Amendment and Corrections

Correction

In rule document 93-7638 beginning on page 17085 in the issue of Thursday, April 1, 1993, make the following corrctions:

1. On page 17086, in the second column, in paragraph 18., in the fifth line, insert "beginning" before "in".

2. On the same page, in the third column, in paragraph 33., in the fifth line, "corrected" should read "correctly revised".

BILLING CODE 1505-01-D

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[OR 44688; OR 030-03-4210-04; GP3-132]

Realty Action; Exchange of Public Lands; Baker County, OR

Correction

In notice document 93-6754 beginning on page 16200 in the issue of Thursday, March 25, 1993, on page 16200, in the second column, in land description T. 8S., R. 43E., in Sec. 35, after "NE¼" insert a comma.

BILLING CODE 1505-01-D

INTERSTATE COMMERCE COMMISSION

[Ex Parte No. 347 (Sub-No. 2)]

Rate Guidelines; Non-Coal Proceedings

Correction

In notice document 93-8376 beginning on page 18416 in the issue of Friday, April 9, 1993, make the following corrections:

1. On page 18416, in the third column, the docket number should read as set forth above.

2. On page 18417, in the second column, after the last line, "model have been resolved." insert the following text:

Environmental and Energy Considerations

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Regulatory Flexibility Analysis

Pursuant to 5 U.S.C. 605(b), we conclude that our action in this decision will not have a significant economic impact on a substantial number of small entities. The purpose of this Notice is to schedule a demonstration of an AAR model for computing maximum reasonable rates and to solicit comments. The economic impact, if any, is not likely to be felt by a substantial number of small entities.

Decided: April 2, 1993.

By the Commission, Chairman McDonald, Vice Chairman Simmons, Commissioners Phillips, Philbin, and Walden.

Sidney L. Strickland, Jr.,

Secretary.

[FR Doc. 93-8376 Filed 4-8-93;8:45 am]

BILLING CODE 1505-01-D

federal register

Friday
April 16, 1993

Part II

Environmental Protection Agency

40 CFR Parts 122 et al.
Water Quality Guidance for the Great Lakes System and Correction; Proposed Rules

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 131, and 132

[FRL 4205–6]

RIN 2040–AC08

Proposed Water Quality Guidance for the Great Lakes System

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: This document provides opportunity for comment on the proposed Water Quality Guidance for the Great Lakes System ("Guidance") developed under section 118(c)(2) of the Clean Water Act (CWA), as amended by section 101 of the Great Lakes Critical Programs Act of 1990 (CPA). This Guidance, once finalized, will establish minimum water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System in the States of New York, Pennsylvania, Ohio, Indiana, Illinois, Minnesota, Wisconsin, and Michigan, including the waters within the jurisdiction of Indian tribes. Today's proposal also is intended to satisfy the requirements of section 118(c)(7)(C) of the Clean Water Act that EPA publish information concerning the public health and environmental consequences of contaminants in Great Lakes sediment and that the information include specific numerical limits to protect health, aquatic life, and wildlife from the bioaccumulation of toxins.

The proposed Guidance specifies numeric criteria for selected pollutants to protect aquatic life, wildlife and human health within the Great Lakes System and methodologies to derive numeric criteria for additional pollutants discharged to these waters. The proposed Guidance also contains specific implementation procedures to translate the proposed ambient water quality criteria into enforceable controls on discharges of pollutants, and a proposed antidegradation policy for the Great Lakes System.

The Great Lakes States and Tribes must adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance. If a Great Lakes State or Tribe fails to adopt consistent provisions within two years of EPA's publication of the final Guidance, EPA will promulgate such provisions within the same two-year period.

DATES: EPA will accept public comments on the proposed Guidance until September 13, 1993. Comments postmarked after this date may not be considered.

A public hearing on the proposed Guidance will be held on August 4 and 5, 1993, in Chicago, Illinois, beginning at 9 a.m. on August 4, 1993. The hearing officer reserves the right to limit oral testimony to 10 minutes, if necessary.

In addition, EPA and the States plan to hold a series of public informational meetings across the Great Lakes Basin to provide a general overview of the various elements in the proposed Guidance. Members of the public should call the following numbers for information on the dates and locations of these meetings: (1) In Illinois, Indiana, Michigan, Minnesota, Ohio and Wisconsin—800–621–8431; (2) in Pennsylvania—215–597–6911; (3) in New York—716–285–8842.

ADDRESSES: An original and 4 copies of all comments on the proposed Guidance should be addressed to Wendy Schumacher, Water Quality Branch (WQS–16J), U.S. EPA, Region V, 77 West Jackson Blvd., Chicago, Illinois, 60604 (telephone: 312–886–0142).

The public hearing on the proposed Guidance will be held in room 331, 77 W. Jackson Blvd., Chicago, Illinois.

Materials in the public docket will be available for inspection and copying at the U.S. EPA Region V Records Center, 77 W. Jackson Blvd., Chicago, Illinois, by appointment only. Appointments may be made by calling Wendy Schumacher (telephone 312–886–0142). A reasonable fee will be charged for photocopies.

Selected documents supporting the proposed Guidance will also be available for viewing by the public at the following locations:

Illinois: Lincoln Library, Lincoln Library Reference Center, 326 South 7th Street, Springfield, Illinois, 62701 (217–753–4945).

Indiana: Indiana Department of Environmental Management, Office of Water Management, 6th Floor, 105 Meridian Street, Indianapolis, Indiana, 46206 (317–232–8671).

Michigan: Library of Michigan, Government Documents Service, 717 West Allegan, Lansing, Michigan, 48909 (517–373–1300); Detroit Public Library, Sociology and Economics Department, 5201 Woodward Avenue, Detroit, Michigan, 48902 (313–833–1440).

Minnesota: Minnesota Pollution Control Agency, Library, 320 Lafayette, St. Paul, Minnesota (612–296–7719).

New York: U.S. EPA Region II Library, room 402, 26 Federal Plaza, New York, New York, 10278 (212–264–2881); U.S. EPA Public Information Office, Carborundum Center, Suite 530, 345 Third Street, Niagara Falls, New York, 14303 (716–285–8842); New York State Department of Environmental Conservation (NYSDEC), room 310, 50 Wolf Road, Albany, New York, 12333 (518–457–7463); NYSDEC, Region 6, 7th Floor, State Office Building, 317 Washington Street, Watertown, New York, 13602 (315–785–2513); NYSDEC, Region 7, 615 Erie Boulevard West, Syracuse, New York, 13204 (315–426–7400); NYSDEC, Region 8, 62 74 East Avon-Lima Road, New York, 14414 (716–226–2466); NYSDEC, Region 9, 270 Michigan Avenue, Buffalo, New York, 14203 (716–851–7070).

Ohio: Ohio Environmental Protection Agency Library—Central District Office, 1800 Watermark Road, Columbus, Ohio, 43215 (614–644–3024); U.S. EPA Eastern District Office, 25809 Central Ridge Road, Westlake, Ohio, 44145 (216–522–7260).

Pennsylvania: Pennsylvania Department of Environmental Resources, 1012 Water Street, Meadville, Pennsylvania, 16335; U.S. EPA Region III Library, 8th Floor, 841 Chestnut Building, Philadelphia, Pennsylvania, 19107–4431 (215–597–7904).

Wisconsin: Water Resources Center, University of Wisconsin-Madison, 2nd Floor, 1975 Willow Drive, Madison, Wisconsin (608–2620–3069).

Selected documents supporting the proposed Guidance are also available by mail upon request for a fee (see section XIII of the preamble for additional information).

FOR FURTHER INFORMATION CONTACT: Kenneth A. Fenner, Water Quality Branch Chief (WQS–16J), U.S. EPA Region V, 77 W. Jackson Blvd., Chicago, Illinois, 60604 (Telephone: 312–353–2079).

SUPPLEMENTARY INFORMATION:

Preamble Outline

I. Background

A. Description of Resource

1. General Statistics
2. Physical Characteristics
3. History of Environmental Degradation
4. Environmental Problems in the Great Lakes System
   a. Nutrients
   b. Toxic Substances

B. Great Lakes Water Quality Agreement

1. History of the Great Lakes Water Quality Agreement
   a. The Boundary Waters Treaty of 1909
   b. The 1972 Great Lakes Water Quality Agreement
   c. The 1978 Great Lakes Water Quality Agreement
   d. The 1987 Amendments to the Great Lakes Water Quality Agreement
2. Major Provisions of the Great Lakes Water Quality Agreement
3. Implementation of the Great Lakes Water Quality Agreement
   a. The International Joint Commission
   b. Provisions for Consolidation and Review

c. Status of Negotiations With Canada on Revising the Specific Objectives

C. Governors' Toxics Agreement

D. Great Lakes Water Quality Initiative

1. Formation of Great Lakes Water Quality Initiative
2. Great Lakes Critical Programs Act of 1990
3. Process After the CPA

E. Elements of the Guidance

1. Water Quality Criteria for the Protection of Aquatic Life
2. Water Quality Criteria for the Protection of Human Health
3. Water Quality Criteria for the Protection of Wildlife
4. Bioaccumulation Factors
5. Antidegradation
6. Implementation Procedures

F. Science Advisory Board Review

G. Other Programs to Protect and Restore the Great Lakes

1. Great Lakes Five Year Strategy
2. Great Lakes Pollution Prevention Action Plan
3. Lakewide Management Plans (LaMPs)
4. Remedial Action Plans (RAPs)
5. Contaminated Sediments
6. Atmospheric Deposition
7. Storm Water
8. Combined Sewer Overflows (CSOs)
9. Discharges of Oil and Hazardous Polluting Substances
10. Nonpoint Sources of Pollution
11. Great Lakes Fish Advisories
12. Environmental Monitoring and Data Management Programs for the Great Lakes
13. Great Lakes Toxic Reductions Initiative Multi-media Management Committee

H. References

II. Regulatory Requirements

A. Scope and Purpose

B. Definitions

C. Adoption of Criteria, Methodologies, and Procedures

D. Application of Methodologies, Policies, and Procedures

1. The Two-Tiered Approach
2. Application of Tier I Methodologies
3. Application of Tier II Methodologies

E. Applicability of the Water Quality Guidance

1. Criteria and Values
   a. Background
   b. Applicability of the Proposed Guidance
   c. Justification for the Proposed Approach
   d. Other Options Considered
2. Implementation Procedures
   a. Applicability of the Proposed Guidance
   b. Justification for the Proposed Approach
   i. Wet-weather Point Source Discharges
   ii. Excluded Pollutants
3. Antidegradation Policies

F. Excluded Pollutants

G. Pollutants of Initial Focus for Criteria Development, and Bioaccumulative Chemicals of Concern

H. Adoption Procedures

I. Interpretation of "Consistent With"

J. Precedential Effect of Elements of the Guidance

K. Endangered Species Act

L. Request for Comments

III. Aquatic Life

A. Introduction and Purpose

B. Tier I Criteria

1. Methodology
2. Selection of Pollutants for Application of Tier I Criteria Methodology
3. Tier I Numeric Criteria
4. Potential Changes to National Guidelines

C. Tier II Values

D. Conformance to the Clean Water Act, Great Lakes Water Quality Agreement and Great Lakes Critical Programs Act of 1990

1. Tier I Aquatic Life Criteria and Methodology
   a. Comparison With the Clean Water Act
   b. Conformance With the Great Lakes Water Quality Agreement
2. Tier II Criteria Methodology
   a. Comparison With the Clean Water Act
   b. Conformance With the Great Lakes Water Quality Agreement

IV. Bioaccumulation Factors

A. Introduction

B. Bioaccumulation Factors

1. Bioaccumulation and Bioconcentration Concepts
2. Existing EPA Guidance
3. The Great Lakes Guidance for BAFs
   a. Measured and Predicted BAFs
   b. Standard Lipid Values
   i. Standard Lipid Value for Human Health BAFs
   ii. Standard Lipid Value for Wildlife BAFs
   iii. Comments Requested
   c. Food Chain Multipliers
   d. Effect of Metabolism on BAFs
   e. Bioavailability
   f. Other Uses of BAFs
4. SAB Comments
5. Relationship of the Guidance to Current EPA Guidance
6. Adoption of Water Quality Standards Consistent with the Proposed Guidance
7. Literature Cited

V. Human Health

A. Introduction

B. Criteria Methodologies

1. Endpoints Addressed by the Human Health Methodologies
2. Mechanism of Action: Cancer and Noncancer
   a. Cancer
   b. Noncancer
3. Choice of Risk Level
4. Acceptable Dose
   a. RAD
   b. ADE
   c. IRIS
5. Exposure Assumptions
   a. Body Weight
   b. Duration of Exposure
   c. Incidental Exposure
   d. Drinking Water Consumption
   e. Fish Consumption
   f. Bioaccumulation Factor (BAF)
   g. Relative Source Contribution
   h. General Considerations
6. Minimum Data Requirements/Tier I and Tier II
   a. Carcinogens
   b. Non-carcinogens
7. Criteria Derivation
8. Proposed Criteria and Values

C. Relationship of the Great Lakes Initiative Guidelines to National Guidelines Revisions

D. Comparison With the Clean Water Act and Great Lakes Water Quality Agreement

1. Tier I Human Health Criteria/Methodology
   a. Comparison With the Clean Water Act
   b. Conformance With the Great Lakes Water Quality Agreement
2. Tier II Criteria Methodology
   a. Comparison with the Clean Water Act
   b. Conformance with the Great Lakes Water Quality Agreement

E. Review of the Great Lakes Guidance by the EPA Science Advisory Board (SAB)

F. Literature Citations

VI. Wildlife

A. Introduction

B. Wildlife Criteria Methodology

1. Wisconsin State Wild and Domestic Animal Criteria
2. Modifications to Wisconsin's WDAC Procedure
3. The Great Lakes Water Quality Initiative Wildlife Criteria Methodology
   a. Parameters of the Hazard Component of the GLWQI Wildlife Criteria Methodology
   i. LOAEL to NOAEL Extrapolations
   ii. Subchronic to Chronic Extrapolations
   iii. Species Sensitivity Factor
   iv. Intraspecies Variability
   v. Alternative Formula for Hazard Component of Equation
   b. Parameters of the Exposure Component of the GLWQI Wildlife Criteria Methodology
   i. Approach Used to Select Representative Species Identified for Protection
   ii. Bioaccumulation Factors
   iii. Exposure Routes Considered

C. Additional Issues

1. Use of Human Health Paradigm
2. Minimum Data Base for Wildlife Criteria Derivation
3. Acceptable Endpoints for Toxicity Studies
4. Use of an Acute to Chronic Conversion Ratio

D. Chemical Selection for Wildlife Criteria Derivation

E. Tier I Wildlife Criteria and Tier II Wildlife Values

F. Comparison With the CWA and Relationship to National Guidance

1. Relationship to Existing National Guidance
2. Relationship to Current Efforts to Provide National Guidance for the Development of Wildlife Criteria

G. Comparison of Wildlife Criteria and Methods to National Program and to Great Lakes Water Quality Agreement

1. "No Less Restrictive" Than the CWA and National Guidance
2. Conformance With the Great Lakes Water Quality Agreement

H. Bibliography

VII. Antidegradation

A. General Discussion/Background

1. Federal Antidegradation Policy and History
   a. History of the Federal Antidegradation Policy
   b. Existing National Antidegradation Policy
   c. Great Lakes States Experience
   d. Alternative Approaches to Assessing Lowering of Water Quality

B. General Outline of GLWQI Antidegradation Process

1. Narrative Flow Chart of Process
2. Preconditions for Implementation of Antidegradation Procedures
3. Steps Preceding an Antidegradation Review
   a. Establish That the Action May Significantly Lower Water Quality
   b. Characterize the Receiving Water

C. Activities Covered by the Great Lakes Antidegradation Guidance

1. Distinction Between High Quality Waters, Outstanding National Resource Waters, and Other Classes of Waters
   a. Existing Federal Policy
   b. GLWQI Guidance
2. Significant Lowering of Water Quality
3. Covers All Pollutants Sources (Point and Nonpoint)
4. Exemptions
5. Discharges of Fill Material in Wetlands

D. Existing Effluent Quality

1. Background
2. Options for EEQ Controls
   a. Option 1: EEQ as Numeric Mass Loading Rate Limitations
   b. Option 2: Narrative Prohibition Coupled with EEQ Notification Requirement
   c. Supplement to Options 1 or 2: Establishment of Discharge Prohibitions to Maintain EEQ
3. Issues
   a. Punishment of Good Performers
   b. Statistical Procedures
   c. Data Availability and Representativeness
   d. Application to Municipalities
   e. Restrictions on Actions Versus Limitations on Pollutants
   f. Statutory Authority for EEQ
   g. Ability to Accommodate a Return to Increased Production Levels Under Antidegradation.
   h. Relationship of EEQ to Implementation Procedure 8

E. De Minimis Lowering of Water Quality

1. Background
2. Detailed Description of De Minimis Test
   a. Specific Tests Included in De Minimis Demonstration
   b. Examples
   i. Example 1
   ii. Example 2
   iii. Example 3
3. Issues
   a. Use of Assimilative Capacity in De Minimis Decision
   b. Fixing Assimilative Capacity at a Date Certain and Choice of Date
   c. Demonstration That No Ambient Change Occurs as a Result of Increased Loading
   d. Use of the Margin of Safety Specified in the Implementation Procedures as a Ceiling on De Minimis Decisions
   e. Multiple De Minimis Lowering of Water Quality by a Single Source

F. Antidegradation Demonstration Components

1. Background and Rationale
2. Hierarchy of Antidegradation Demonstrations
3. Identification of Prudent and Feasible Pollution Prevention Alternatives to Prevent or Reduce the Significant Lowering of Water Quality
   a. Substitution of BCCs with Non-bioaccumulative and/or Non-toxic Substances
   b. Application of Water Conservation Methods
   c. Waste Source Reductions Within Process Streams
   d. Recycle/Reuse of Waste By-products, Either Liquid, Solid, or Gaseous
   e. Manufacturing Process Operational Changes
4. Alternative or Enhanced Treatment Alternatives That Eliminate the Significant Lowering of Water Quality
5. Social or Economic Development Demonstration
   a. Baseline Situation
   b. Net Positive Impact
   c. Other Developments
6. Special Remedial Action Provision
7. Issues
   a. Other Options Considered for Determining if Significant Lowering of Water Quality is Necessary
   b. Economic Recovery
   c. Best Available Technology
   d. Mandatory Expenditures for Alternative or Enhanced Treatment Techniques
   e. Antidegradation Decision Presumption Against the Significant Lowering of Water Quality

G. Special Antidegradation Provisions for Lake Superior

1. Background
2. Effect
   a. Relationship to Other Antidegradation Requirements
   i. Example
   b. Lake Superior Basin-Outstanding National Resource Waters
   c. Lake Superior Bioaccumulative Substances of Immediate Concern

H. Offsets

I. Incorporation Into State Water Quality Standards

VIII. General Implementation Procedures

A. Site-Specific Modifications to Criteria

B. Variances From Water Quality Standards for Point Sources

1. Current EPA Policy
2. GLWQI Proposal (40 CFR part 132, Appendix F, Procedure 2)
3. Applicability
4. Maximum Timeframe
5. Conditions to Grant a Variance
6. Timeframe to Submit Application
7. Public Notice of Preliminary Decision
8. Final Decision on Variance Request
9. Incorporating State- or Tribal-approved Variance Into Permit
10. Renewal of Variance
11. EPA Approval
12. State or Tribal Water Quality Standards Revisions
13. Consistency With the CWA and Conformance With the GLWQA
    a. Consistency With the Clean Water Act
    b. Conformance With the Great Lakes Water Quality Agreement
14. Options Considered
15. Request for Comments

C. Total Maximum Daily Loads

1. Background
2. National Approach
   a. General Approach to TMDL Development
   b. Phased TMDLs
   c. Pollutant Degradation
   d. Pollutant Transport
3. Development of the Proposed Guidance
   a. The Proposed Guidance
   b. Overview of Option A and Option B
4. General Conditions of Application
   a. General Condition 1
   b. General Condition 2
   c. General Condition 3
   d. General Condition 4
   e. General Condition 5
   f. General Condition 6
   g. General Condition 7
   h. General Condition 8
   i. General Condition 9
   j. General Condition 10
   k. General Condition 11
5. Special Provisions for BCCs
   a. Reason for Restricting Discharge of BCCs
   b. Elimination of Mixing Zones for BCCs
   c. New Sources
   d. Mixing Zones During the Ten Year Phase Out
   e. Exception to the Ten Year Phase Out of Mixing Zones
6. TMDLs for Open Waters of the Great Lakes
   a. Point Source Mixing Zones for Chronic Criteria and Values
   b. Calculating Load Allocations
   c. Protection From Acute Effects
   d. Procedures When High Background Concentrations are Present
   e. Margin of Safety
   i. Chronic Criteria and Values
   ii. Acute Criteria and Values
7. TMDLs for Discharges to Tributaries
   a. Steady State Mass Balance Approach Common to Both Options

b. Design Flows Common to Both Options
c. Overview of Option A
i. Load Inventory
ii. Loading Capacity
iii. Basin Margin of Safety
iv. Load Reduction Targets
v. Basin Allocations
vi. Site-specific Cross-checks
vii. Establish Final Allocations
viii. Monitoring Provisions
d. Overview of Option B
i. Source-specific TMDLs
ii. Mixing Zone Capacity
iii. Background Loadings
iv. Formula Modification Based on Mixing Zone Studies
v. Limitation of Use of Source-specific TMDL Formula
e. Pollutant Degradation
8. Pollution Trading Opportunities
9. State Adoption
10. Summary of Other Options Considered
11. Request for Comments

D. Additivity

1. Introduction
2. Approaches Considered
a. Aquatic Life
b. Human Health—Carcinogens
c. Human Health—Non-carcinogens
d. TEFs and BEFs for Chlorinated Dibenzo-p-dioxins (CDDs) and Chlorinated Dibenzoforans (CDFs)
e. Wildlife
3. Request for Comment on Approach Considered for Implementing the States' Narrative Criteria
4. Request for Comment on Alternative Approach
5. Request for Comments

E. Reasonable Potential for Exceeding Numeric Water Quality Standards

1. Existing National Rules and Guidance
a. Excursion Above the Water Quality Standard
b. Reasonable Potential for Excursion Above the Water Quality Standard
c. No Reasonable Potential for Excursions Above the Water Quality Standards
d. Inadequate Information
2. Proposed Procedure 5
a. Developing Preliminary Effluent Limitations
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Appendix to the Preamble—Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria

I. Background

A. Description of Resource

1. General Statistics

The Great Lakes, comprising Lakes Superior, Michigan, Huron (including Lake St. Clair), Erie, and Ontario, are an important part of the physical and cultural heritage of North America. From the western tip of Lake Superior to the eastern shores of Lake Ontario, the Great Lakes span over 750 miles. Termed freshwater or inland seas by early explorers on the North American continent, the Great Lakes provide water for consumption, transportation, power, recreation and a host of other uses by aquatic life, wildlife and humans. The Great Lakes are one of the largest surface systems of fresh water on earth, containing roughly 20 percent of the world's fresh water supply and 95 percent of the freshwater of the United States. Only the polar ice caps and Lake Baikal in Siberia contain more fresh water.

The Great Lakes System includes the five Great Lakes and all streams, rivers, lakes and other bodies of water that are within the drainage basin of the Great Lakes, including all connecting channels (the Saint Mary's River, Saint Clair River, Detroit River, Niagara River and the Saint Lawrence River to the Canadian Border). The Great Lakes System spans waters in eight States—New York, Pennsylvania, Ohio, Indiana, Illinois, Michigan, Wisconsin and Minnesota—and parts of the Canadian Province of Ontario. The Great Lakes region is currently home to more than 40 million people, including 20 percent of the United States population and 50 percent of the Canadian population. Over 23 million of these people depend upon the Great Lakes for drinking water.

The Great Lakes Basin Ecosystem—the interacting components of air, land, water and living organisms, including humans, that live within the Great Lakes drainage basin—supports hundreds of species of aquatic life, wildlife and plants. Over 4,500 miles of coastline, six National Parks and Lakeshores, six National Forests, seven National Wildlife Refuges, and dozens of State parks, forests, and sanctuaries are part of this System.

Some of the world's largest concentrations of industrial capacity are located in the Great Lakes System. The Soo Locks, located between the sister cities of Sault Ste. Marie, Michigan and Ontario, handle more tonnage of commercial cargo than the Suez and Panama Canals combined. Sixty-four of the 1,000 power plants located within the United States are situated in Great Lakes coastal counties and generate 20 billion kilowatt hours of electricity each year. Approximately 25 percent and seven percent of the total agricultural production of Canada and the United States, respectively, occurs within the Great Lakes System. The Great Lakes System also provides recreational and economic benefits from the sport fisheries, boating, campgrounds, and resorts associated with it. The Great Lakes System is a unique natural resource affording habitat to a vast array of living organisms, and inestimable aesthetic beauty for the peoples of the United States and Canada.

2. Physical Characteristics

The Great Lakes are divided into the Upper Lakes, Lakes Superior, Huron and Michigan, and the Lower Lakes, Lakes Erie and Ontario. All of the lakes except Lake Michigan are binational, that is, their waters are shared by the United States and Canada. Only Lake Michigan is located entirely within the United States.

In spite of their large size and substantial volume of fresh water, the Great Lakes are sensitive to the effects of a wide range of pollutants that enter the Lakes through both point and nonpoint sources. The sources of these pollutants include, but are not limited to, the agricultural runoff of soils and farm chemicals from rural lands, city wastes, industrial discharges, and leachate from disposal sites. The large surface area of the Great Lakes also exposes them to the direct atmospheric deposition of pollutants from rain, snow and dust that settle onto the lakes' surfaces.

Lake Superior is the largest, deepest, and coldest of the Great Lakes, and has the longest retention time, the average time it takes for a molecule of water to exit the system, at 173 years. It is also the most pristine of the Great Lakes, having not experienced the vast industrial and agricultural usage of the rest of the Great Lakes System. Lake Michigan is the second largest lake, with a retention time of 62 years. The Lake Michigan basin is characterized by sparse population in its northern reaches and some of the most urbanized areas in the Great Lakes System along its southern shores. Lake Huron, with a retention time of 21 years, is the third largest of the lakes, and has a mixture of industrial and agricultural areas. Two-thirds of its watershed is still forested.

Lakes Erie and Ontario have significantly smaller retention times of 2.7 and 7.5 years, respectively, as compared to the Upper Lakes. Lake Erie is the smallest and the shallowest of the lakes, and is the most susceptible to the effects of urban and agricultural activities. The Lake Erie basin supports an intensive agricultural base. Lake Ontario, the eastern-most lake, eventually receives all of the waters from the other lakes. The Canadian shore of Lake Ontario is heavily urbanized, while the U.S. side is characterized by a lower degree of industrial activity, and moderate farming.

Outflows from the Great Lakes are relatively small (less than one percent per year) in comparison to the total volume of water the lakes contain. Pollutants that enter the lakes through a variety of pathways—by direct discharge or nonpoint discharge into the open waters of the Great Lakes, through tributaries, or from atmospheric deposition—are not readily flushed from the Great Lakes System as in a riverine system. They can be made relatively inaccessible to living organisms through volatilization, burial in the sediments, and degradation. Pollutants re-enter the water column through resuspension of bottom sediments, dredging, storm events, or volatilization cycles, where they are once again accessible to living organisms. These recycling phenomena add to the overall retention time of chemicals within the Great Lakes System (Andre et al., 1993; Beltran, 1992; Richardson, 1993; U.S. EPA, 1989). During the periods that chemicals remain in the lakes, certain pollutants tend to bioaccumulate in organisms, becoming concentrated at levels in the organisms which greatly exceed the

ambient concentrations in the open waters of the Great Lakes.

3. History of Environmental Degradation

Early settlement and related economic activities drastically changed portions of the Great Lakes System. The vast tracts of timber provided materials for ship building, construction, furniture and specialty products. Paper making from pulpwood developed later, with the United States and Canada leading the world's production. Today, reforestation throughout the Great Lakes System is a critical ecosystem issue.

Commercial fishing began in the Great Lakes about 1820, and expanded rapidly. The largest harvests were recorded in 1889 and 1899 at about 147 million tons annually. However, by the 1880s preferred species were on the decline, and the overall value of the Great Lakes fishery has declined dramatically due the predominance of small, relatively low value species. Over-fishing, pollution, stream and shoreline habitat destruction, and the introduction of exotic species have all contributed to the decline of the Great Lakes fishery.

The rapid, large scale clearing of land for agricultural purposes caused deep changes in the Great Lakes Basin Ecosystem. Soils stripped of vegetation washed away to the Lakes, clogging tributaries and deltas, and altering the flows of waterways and changing flood zones. Synthetic fertilizers and chemicals to control pests were increasingly used to enhance production. One of the earliest pesticides, DDT, was subsequently identified as causing reproductive failures in some species of birds. The combined use of synthetic fertilizers, existing sources of nutrient-rich organic pollutants (such as untreated human wastes from cities), and phosphate detergents caused widespread algal blooms, resulting in eutrophication.

Industrialization followed the agrarian settlement of the Great Lakes. During this period, virtually untreated wastes were introduced into the waters of the System. The growing urbanization that accompanied the industrial development of the Great Lakes System added to the overall degradation of water quality. Nuisance conditions, such as bacterial contamination, putrescence, and floating debris in rivers and nearshore areas, were increasingly common. On some occasions, these conditions caused fatal epidemics of waterborne diseases such as typhoid.

With the progressive development of heavy industry, many new chemical substances were introduced into the Great Lakes System. Approximately 13,000 factories that refine petroleum and manufacture products as plastics, chemicals, paints, iron, steel, cars, pulp and paper are located within the Great Lakes basin, including 3,800 factories that discharge waste water directly to the waters of the Great Lakes System. Most of the remaining 9,000 factories discharge wastes indirectly through municipal wastewater treatment plants. Metals, organic compounds and other substances used in industrial processes have entered the Great Lakes System and continue to contribute to the overall degradation of water quality.

4. Environmental Problems in the Great Lakes System

a. *Nutrients.* In the late 1960s, growing public concern about the deterioration of water quality in the Great Lakes stimulated increased research into the causes of environmental degradation. For example, increased nutrients to the lakes had dramatically stimulated the growth of green plants and algae. Decomposition of these organic materials resulted in decreased levels of dissolved oxygen in bottom waters. This process, called eutrophication, had become increasingly common in shallow bays throughout the Lakes, and Lake Erie in particular. As oxygen levels continued to drop, certain species of insects and fish, such as mayflies, trout and walleyed pike were essentially displaced from affected areas of the Great Lakes Basin Ecosystem. Pollution tolerant species, requiring less oxygen, such as sludge worms and carp, replaced the original species. Lake-wide changes in the type of bottom-dwelling organisms and fish, as well as in species of algae, were good indicators of overall oxygen depletion in the lakes.

Environmental managers determined that a lakewide approach was necessary to adequately control the problems caused by accelerated eutrophication. By the late 1960s, United States and Canadian regulatory agencies were in agreement that limiting the loadings of phosphorus was the key to controlling excessive algal growth and, therefore, chronic eutrophication. An effluent limit of one µg/L of phosphorus was imposed on all major (greater then 1 million gallons per day) municipal sewage treatment facilities in the Great Lakes basin. Some States took additional steps, such as limiting the phosphorus content in household detergents, to cut phosphorus discharges to the Great Lakes. In the late 1970s, the United States and Canadian Governments undertook the development of phosphorus budgets for each lake considering point source loadings and nonpoint source runoff loadings.

As a result of all of these efforts, open lake phosphorus concentrations have declined. To date, phosphorus loadings from municipal sewage treatment facilities have been reduced by an estimated 80 to 90 percent. These reductions have resulted in dramatic improvements in nearshore water quality and measurable improvements in open lake conditions. For Lakes Huron, Michigan and Superior, phosphorus concentrations have historically been near or below established targets. In Lakes Erie and Ontario, phosphorus concentrations were more than twice the target values in the early 1970s, but have been reduced to levels at or below the targets since the late 1980s. At this time, the United States is meeting its phosphorus load commitments for each lake. Over the long term, oxygen depletion rates have declined, with the rates of depletion for recent years among the lowest reported.

EPA and the Great Lakes States recognize that existing efforts to maintain or further reduce phosphorus loadings must continue. The proposed Great Lakes Water Quality Guidance does not expressly address phosphorus loadings to the Great Lakes, however, because separate ongoing programs have been established to address this issue.

b. *Toxic Substances.* Toxic contamination of the Great Lakes System has significantly impacted the environment both in and around the lakes, and the health of the aquatic life, wildlife and humans that depend upon the lakes for food and drinking water. Toxic pollutants, including metals and man-made organic chemicals, can be acutely poisonous in relatively small amounts and can be injurious, through chronic exposure, in minute concentrations. Many contaminants present in the Great Lakes System have the potential to increase the risk of cancer, birth defects, genetic mutations and reproductive impacts through long-term exposure. Adverse impacts on fish, bird, and mammal populations in the Great Lakes associated with the effects of toxic chemicals include: Cancer, death, eggshell thinning, population declines, reduced hatching success, abnormal behavior (such as abandonment of nests), infertility, birth defects (such as crossed beaks and club feet) and illnesses such as chick edema. They also include less visible effects on body chemistry, including abnormalities in the thyroid, liver and endocrine systems.

Once introduced into the Great Lakes—whether by point sources, atmospheric deposition, contaminated sediments, ground water, or surface runoff—some toxic substances have physical, chemical, or biological properties that make the chemicals persist for extended periods in the aquatic environment without degrading or otherwise disappearing, and bioaccumulate through the food chain of the Great Lakes System. While the concentrations of these chemicals in water may be so low as to be undetectable by available analytical techniques, persistence and bioaccumulation can increase the levels of these contaminants to toxic concentrations. These persistent bioaccumulative toxic chemicals are of particular importance to the Great Lakes Basin Ecosystem due to the long retention times of the individual lakes and the cycling of toxics from one component of the ecosystem to another.

Several characteristics of the Great Lakes result in their being particularly susceptible to relatively nondegradable, lipophilic chemicals. These characteristics include: (1) Long hydraulic retention times (relatively closed systems); (2) low biological productivity; (3) low suspended solids concentrations; (4) great depth; and (5) the presence of self-contained fish and wildlife populations dependent on the Great Lakes System for their water and food supply. Taken together, these characteristics result in such pollutants remaining in the system for long periods of time and bioaccumulating in fish and wildlife at concentrations which are orders of magnitude above ambient concentrations in the water column.

Physical transport is one pathway by which pollutants are removed from the Great Lakes Basin Ecosystem. Because of the long hydraulic retention times of the Great Lakes, however, downstream transport of pollutants is not a significant pathway of removal, and as discussed below, long retention times are but one of several attributes which result in recycling and prolonged recovery rates for the Great Lakes. The hydraulic residence times for the Great Lakes, based on present diversion rates, range from 2.7 years for Lake Erie to 173 years for Lake Superior.

The main processes which account for loss of a pollutant from the active compartments of the lakes are burial, degradation, volatilization and advection (or diffusion) out of the watershed. Of these processes, the settling and subsequent burial of many persistent particulate-associated pollutants is believed to be a greater factor in the removal of the pollutants from the water column in the deeper Great Lakes than is advection, degradation and volatilization. However, recent evidence from Lake Superior also strongly implicates volatilization as a major pathway for the removal from the water column of some PCB congeners (Eisenreich, 1992).

Hydrophobic pollutants preferentially sorb to biotic and abiotic particles in the water column. Both types of particles will sink and transport pollutants to the bottom sediments. Because of their low biological productivity, however, the Great Lakes are very efficient at cycling nutrients and carbon. Therefore much, if not most, of the pollutant mass associated with biotic particles is either consumed by higher trophic levels and bioaccumulated up the food chain, or is released back to the water column as these particles are degraded by bacterial action. Pollutants sorbed to abiotic particles may reach the bottom sediments, but this is a slow process ranging from months to years due to the low suspended particulate concentrations and net sedimentation rates. Particles which do reach the bottom sediments are subject to resuspension resulting from storm events and other disturbances.

The affinity of many organic pollutants for binding onto suspended particles is well established. Partition coefficients (K_d) between particulate and dissolved phases for PCBs in Lake Superior, for example, range from roughly from 10^4 to 10^7 with a mean about 10^6. For a pollutant with a $K_d=10^6$, and a characteristic particle settling rate of 1 m/day, rough rate calculations indicate that removal of that pollutant from the water via settling could occur in 1.2 years in Lake Superior and in less than 1 year for the other Great Lakes (Eadie and Robbins, 1987). Of course many other factors operate to control the particle-pollutant dynamics. Partition coefficients vary with pollutants, with the organic content of the suspended solids, and with the concentration of the solids in the water column. The particle settling times for the Great Lakes are far shorter than the long hydraulic retention times, however, meaning that the Great Lakes are effectively closed systems with regard to physical transport of a pollutant out of the watershed via mass water flows through the connecting channels and St. Lawrence River.

Once a particle-associated pollutant reaches the lake floor it is not immediately incorporated into the sediments. Rather, particles accumulate during the stratified season in a benthic nepheloid layer (BNL) near the sediment surface. This is a feature common to all the Great Lakes. Also contributing to the composition of the BNL are resuspension of surficial sediments and transport of sediments from more shallow regions of the lakes. Within the BNL, however, particulate organic matter is rapidly degraded and little becomes incorporated into the sediments. The result is a rapid release and transport of pollutants from the water column to the sediments. Studies show a portion of these pollutants are returned to the water column by resuspension during autumn mixing of the water column (Baker and Eisenreich, 1989; Hermanson et al., 1991; Durham and Oliver, 1983). Net residence time of pollutants in the water column of the Great Lakes is therefore longer than the net time for suspended particles to settle into sediment.

Organic pollutants can eventually become buried in the bottom sediments. Evidence from dated sediment cores taken from Lake Superior, Lake Michigan, and Lake Ontario indicates that PCBs began accumulating approximately in 1930 and that maximum concentrations are now found in sediments dated from 1960 through the mid-1970s (Hermanson et al., 1991). In areas of the Great Lakes which experience significant sediment accumulation, more recent sediments contain lower concentrations of PCBs than the peak, but still greatly elevated over the levels representing the 1930s.

Pollutants in the bottom sediments, as well as those sorbed to particulates in the water column, provide a reservoir for loadings to the water column. As dissolved phase pollutants are removed through processes such as volatilization, pollutants desorb from bottom and suspended sediments to maintain the dissolved phase concentrations in the water column. Pollutants in the dissolved phase are readily available for uptake by aquatic organisms. Once pollutants are present in aquatic organisms they can biomagnify in the food chain.

Recent research indicates that most of the PCB mass in Lake Superior is recycling between dissolved phase water column, particulate phase water column, bottom sediments and back to the dissolved phase in the water column (Eisenreich, 1992). As the recycling occurs a portion of the PCB mass is bioaccumulated by the food chain. This recycling, even absent continued inputs from land or air sources, provides an internal loading source.

Overall, the water column in the Great Lakes initially responds rapidly to decreases in loadings of pollutants, but sediment-water interactions extend the overall response time significantly. For

example, data from mass balance studies and inventories in the Great Lakes System indicate that there is a significant reservoir of PCBs in the soils and sediments that will continue to release PCBs into the environment at significant rates for decades (Andre et al., 1993; Beltran, 1992; Richardson, 1993; U.S. EPA, 1989). While concentrations of persistent, bioaccumulative pollutants may eventually decline, for the Great Lakes the rate of decline will occur much slower than in systems with lower hydraulic retention times or more productive systems with greater sedimentation loading rates. Once released to the Great Lakes Basin Ecosystem, toxic substances that are slowly degrading and bioaccumulative will cycle within the system for decades, exerting biological effects and presenting relatively high levels of risk to aquatic life, wildlife and humans which inhabit the basin. An example of a pollutant class that is highly persistent and bioaccumulative is polychlorinated biphenyls (PCBs), which have estimated half lives for biological degradation of months up to several years, and which bioaccumulate in the food chain to levels 1,800,000 times the concentration in the water column (Eisenreich et al., 1989; Ballschmitter et al., 1989). Continued or new inputs of such pollutants serve to exacerbate impairments of beneficial uses.

The rapid decline of PCB concentrations in lake trout from Lake Michigan during the latter half of the 1970s reflects the relatively rapid response of the water column to decreases in loadings. Hydraulic transport of the pollutant from Lake Michigan, with a hydraulic residence time of 62 years, into Lake Huron has little effect on PCB concentrations in the water and fish. Rather, internal responses and processes that operate in the Great Lakes because of their depth and long hydraulic residence times control the pollutant concentrations in response to loadings.

PCB concentrations in Lake Michigan lake trout declined from a maximum of 22.9 mg/kg in 1974 to 5.6 mg/kg in 1982 (DeVault, et al., 1986; DeVault, 1993a) (Figure I–1). The pattern of decline through 1982 is consistent with first order kinetics calculations (DeVault et al., 1986). Beyond 1982, however, the observed PCB concentrations in fish tissue collected in 1984, 1988, and 1990 are significantly higher than levels predicted by first order rate constants calculated from the 1974–1982 period (DeVault, 1993a). Thus, while PCB concentrations are still declining through 1990, the rate of decline is slowing and may be leveling off, resulting in concentrations continuing well above water quality criteria. Studies on biodegradation indicate that the most highly chlorinated (least toxic) forms of PCBs are degraded first, leaving the most toxic forms behind. Laboratory experiments designed to provide optimal conditions for microbial activity have not been able to achieve complete PCB dechlorination, suggesting that the remaining forms of PCB may persist indefinitely (Adler et al., 1993).

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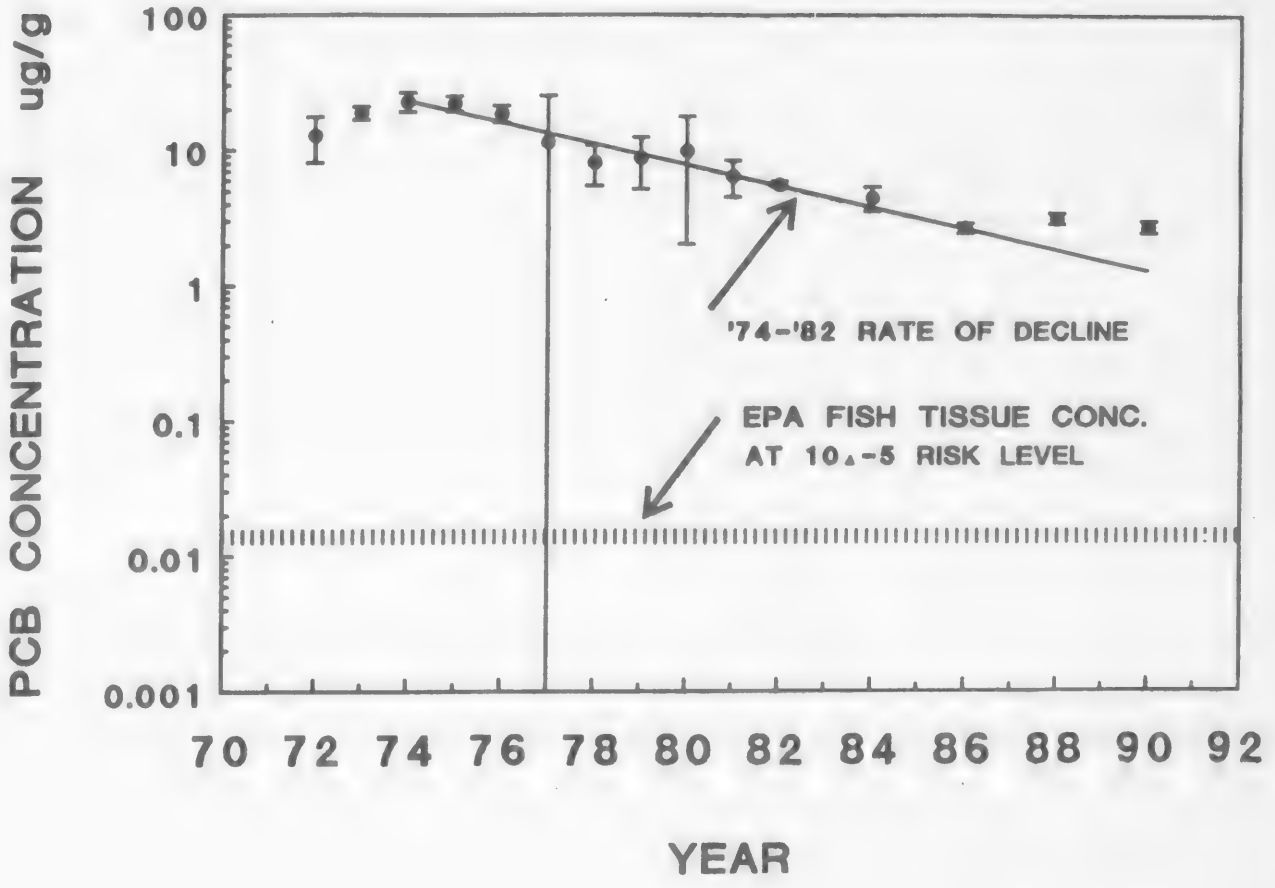
Figure I-1: Total PCB concentration in Lake Michigan lake trout (mean and 95% confidence interval).



Source: DeVault, et al., 1986; DeVault, 1993a.

The slowing in the rate of decline of PCBs in fish tissue is also supported by coho salmon data (DeVault et al., 1988; DeVault, 1993b) (Figure I–2). Because coho are stocked, and are in the lake for only 18 months, they respond much faster to changes in water column concentrations than lake trout, which have an average life span of 6 years. PCB concentrations in coho salmon have been relatively constant in all the Great Lakes since the mid 1980s, with the exception of a general decline in Lake Ontario (DeVault et al., 1988; DeVault 1993b). A similar situation can be seen for PCBs in Lake Superior lake trout (Figure I–3).

Patterns of decline in DDT concentrations in Lake Michigan lake trout are shown in Figure I–4. Data on concentrations of DDT in coho salmon across all the lakes are shown in Figure I–5 (DeVault et al., 1986; DeVault et al., 1988; DeVault, 1993a; DeVault, 1993b). The DDT levels in coho salmon are below levels corresponding to 10–5 mortality risk in all lakes except Lake Ontario. For lake trout, the DDT level in 1990 was substantially above the level corresponding to the 10–5 risk level.

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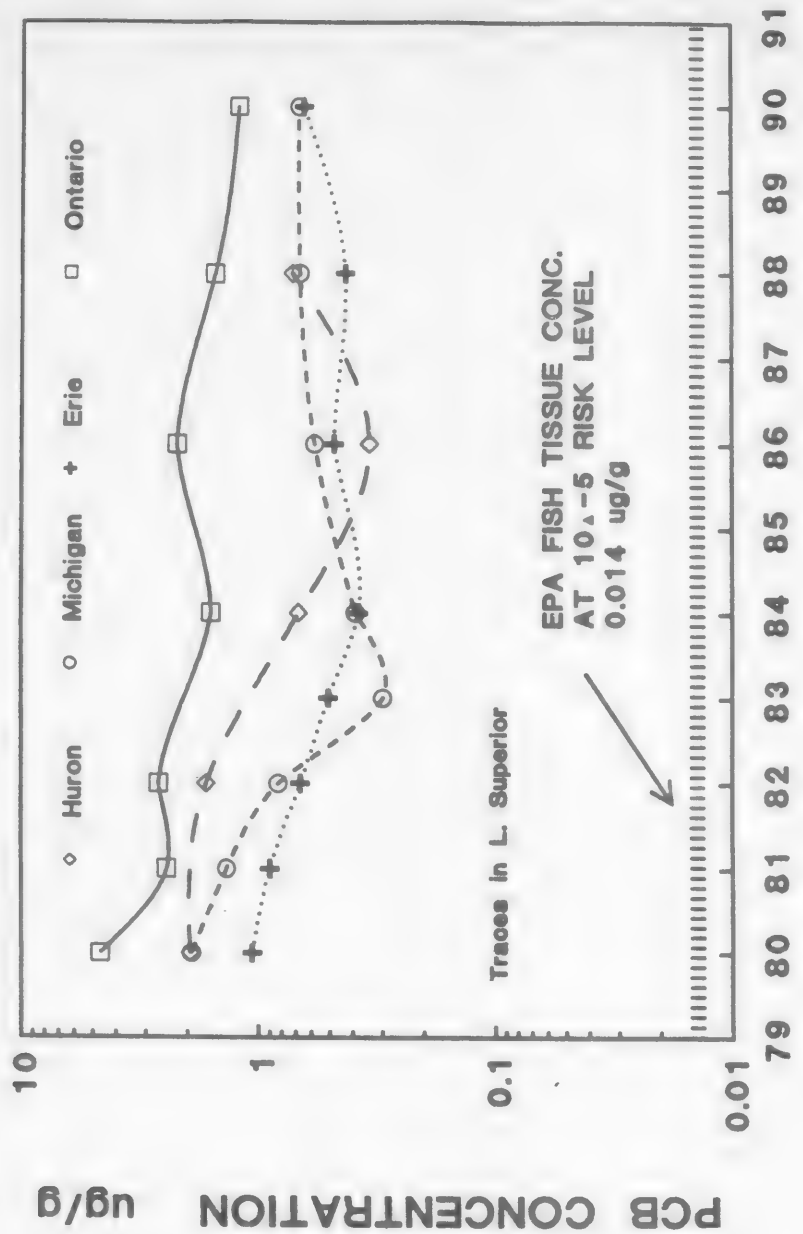
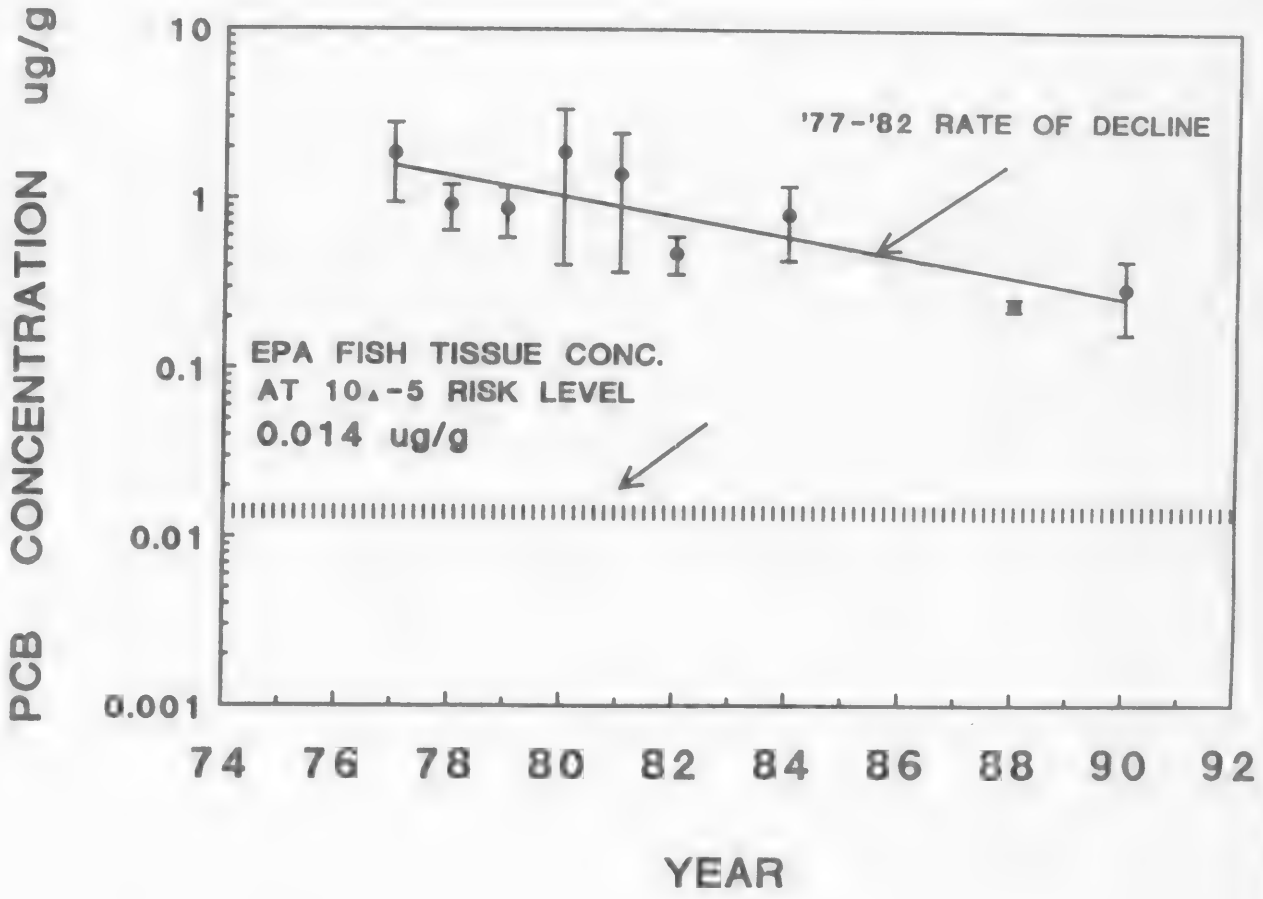
Figure I-2: PCB concentration in coho salmon (μg/g).



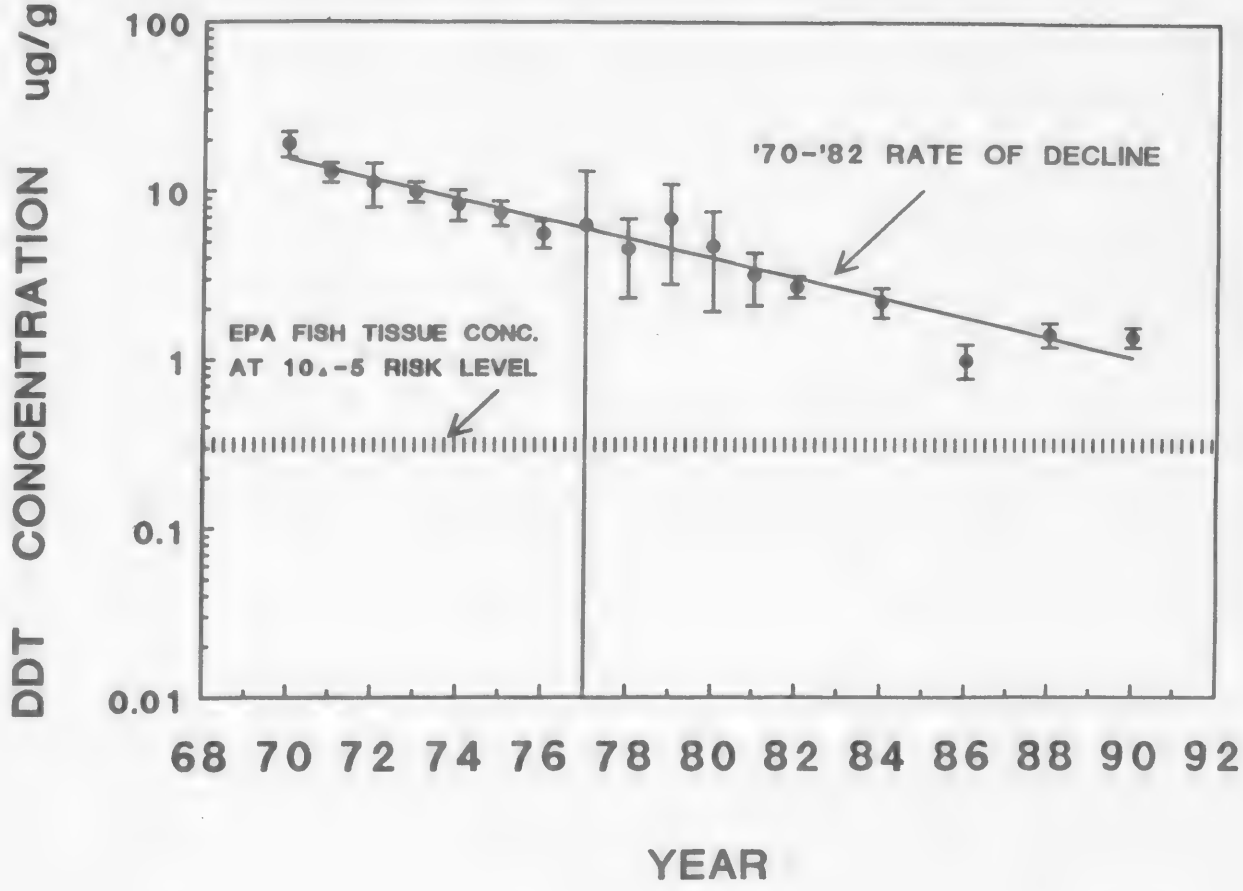
Source: DeVault et al., 1988; DeVault, 1993b.

Figure I-3: PCB concentration in Lake Superior lake trout (μg/g).



Source: DeVault, et al., 1986; DeVault, 1993a.

Figure I-4: DDT concentration in Lake Michigan lake trout (mean and 95% confidence interval)



Source: DeVault, et al., 1986; DeVault, 1993a.

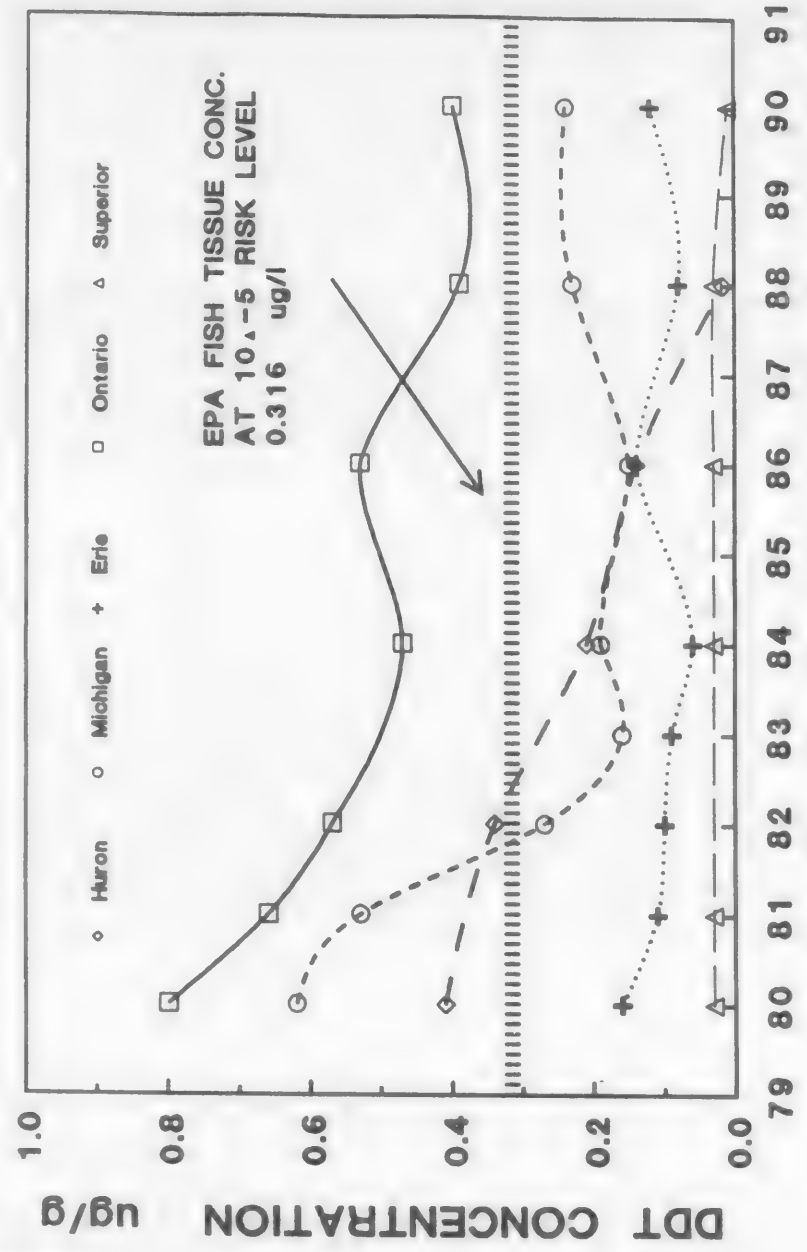


Figure I-5: DDT concentration in coho salmon (μg/g).

Source: DeVault et al., 1988; DeVault, 1993b.

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These substances appear to be approaching equilibrium in the Great Lakes System at unacceptably high levels due to continuing loadings from a variety of sources, such as: (1) Historically contaminated sediments in the embayments as well as the open lakes; (2) tributary inputs resulting from point sources, spills and direct runoff from urban and rural areas, and/or resuspension from contaminated sediments; and (3) atmospheric deposition of pollutants. Concentrations measured in 1990 for PCBs and chlorinated pesticides exceed the fish tissue concentrations that correspond to current EPA 304(a) water quality criteria by several orders of magnitude (Table I–1) (DeVault 1993a). If a new equilibrium is being reached given current mass loadings, then substantial further reductions in mass loadings to the lakes will be necessary to eliminate fish advisories.

TABLE I–1.—COMPARISON OF RECENT MEASURED FISH TISSUE CONCENTRATIONS IN LAKE MICHIGAN LAKE TROUT AGAINST CALCULATED FISH TISSUE CONCENTRATIONS CORRESPONDING TO CURRENT EPA SECTION 304(A) AMBIENT WATER CRITERIA AT 10^{-5} RISK LEVEL.

Substance	1990 measured fish tissue concentration (mg/kg) (mean and 95% confidence interval)	Calculated fish tissue concentration (mg/kg) corresponding to 304(a) criteria
PCBs	2.72 (2.45 – 2.99)	0.014
DDT/DDE	1.39 (1.20 – 1.58)	0.316
Chlordane	0.44 (0.36 – 0.52)	0.083
Dieldrin	0.198 (0.16 – 0.20)	0.0067

Source: DeVault, et al., 1986; DeVault, 1993a.

Within the Great Lakes basin, an ecosystem approach to environmental management has been adopted by U.S. and Canadian agencies whereby physical, chemical and biological aspects of the aquatic system are considered concurrently, rather than in isolation. This approach is dictated largely due to the closed nature of the Great Lakes Basin Ecosystem. As noted above, persistent bioaccumulative pollutants tend to remain within the system for long time periods, recycling among various compartments (e.g., water, sediment, biota). As a result, the residence time of the pollutants may be several times longer than life spans of even relatively long-lived species, such as lake trout and fish-eating birds. This is in contrast to other aquatic systems (e.g., small lakes, rivers, or marine coastal areas) where once the pollutant load to the system is stopped the pollutants are generally removed from the system relatively quickly through such mechanisms as hydraulic transport out of the watershed, dilution through tidal effects, or burial because of high productivity and high sedimentation rates. Thus, in such other aquatic systems pollutants are not present in the ecosystem long enough to affect successive generations of the biota (i.e., the pollutant is removed within one life-cycle of the top predators). Three examples illustrate the uniqueness of the Great Lakes Basin Ecosystem in this regard: Lake trout, colonial birds, and bald eagles.

In the Great Lakes, the lake trout is the classic example of a key species, fundamentally important to the naturally-evolved aquatic community. Lake trout are very long lived (some live longer than 25 years), and while their populations have been devastated by overharvesting and the introduction of the sea lamprey, these fish are also being subjected to a variety of impairments from toxic pollutants.

Past evidence indicates ambient levels of PCBs in the Great Lakes could impair reproduction in lake trout. When nine groups of lake trout fry were exposed for six months to concentrations of PCB and/or DDE similar to that in water and zooplankton in Lake Michigan in 1975, mortalities in the nine exposed groups were 40.5 percent to 114 percent greater than in the control group. These data suggest that if lake trout had spawned successfully in Lake Michigan in the mid-1970's, nearly twice as many of the fry would have died within the first 6 months than if no pollutants were present. However, more recent efforts to estimate the extent to which fish yields (i.e., harvestable catches) are being compromised by present levels of pollutants in the Great Lakes System are inconclusive. Most biological consequences of fish exposure to pollutants have been measured at the physiological or organism level rather than the population level, so it is difficult to determine the extent to which current pollutant concentrations in the Great Lakes may be inhibiting the ability of this species to re-establish viable, self-sustaining populations.

Several fish-eating bird species are at greater risk from exposure to pollutants in the Great Lakes than in other aquatic systems because their foraging range is entirely within the Great Lakes basin for all or part of each year. Species of fish-eating birds known to be affected by pollutants in the Great Lakes include the double-crested cormorant, black-crowned night heron, osprey, herring gull, common tern, Forster's tern, and bald eagle. Colonial waterbirds of the Great Lakes have been shown to bioconcentrate pollutants from their food (i.e., fish) 20 to 30 fold.

The Forster's tern, designated as threatened or endangered, is sensitive to PCBs, chlorinated dioxins and furans, and is limited to marshy embayments such as Green Bay, Saginaw Bay and Lake St. Clair (all of which are experiencing problems with bioaccumulative organic pollutants). In a comparative study of Forster's terns colonies on Green Bay (Lake Michigan) and Lake Poygan (a relatively uncontaminated lake approximately 50 miles from Green Bay, but still in the Green Bay watershed), the Green Bay colonies were severely stressed by toxic pollutants. The median equivalents of TCDD (2,3,7,8-tetrachlorodibenzo-*p*-dioxin) were almost 11 times greater in tern eggs from Green Bay than Lake Poygan (2175 versus 201 pg/g); the hatching success of sibling eggs was 75 percent lower at the Green Bay colonies; hatchlings from laboratory incubations

of Green Bay eggs weighed approximately 20 percent less than those from Lake Poygan; and the ratio of liver weight to total weight was 26 percent greater. Also, nest abandonment and egg disappearance were substantial at Green Bay, but not at Lake Poygan.

The bald eagle is one of the most highly visible symbols of the effect of toxic pollutants in the Great Lakes basin. The total number of active nests along the Great Lakes shoreline in Wisconsin and Michigan in 1970 was only five, compared to an estimated density of one pair per every 8 to 16 km of shoreline before European settlement. Between 1961 and 1970, shoreline nests in these states were successful only 10 percent of the time, with an average reproduction of only 0.14 fledgling per nest, compared to stable, inland populations with 50 percent success rates and an average of 0.7 young per nest. Declines of bald eagle populations in the Great Lakes states were associated with a thinning of egg shells of at least 12 percent. Furthermore, significantly greater concentrations of PCBs, DDE, and dieldrin were found in eagle eggs along the Great Lakes shoreline between 1969 and 1986 than in eggs from inland nests (Table I–2).

TABLE I–2.—CONTAMINANT CONCENTRATION (PPM) IN BALD EAGLE EGGS FROM GREAT LAKES SHORELINE NESTS AND FROM INLAND SITES

Nest site	Years	PCB	DDE	Dieldrin
L. Superior	'69–'82	6.8–80.7	12.7–39.5	0.42–1.1
	'86	12.9–14	2.4–9.5	0.18–0.51
Wisconsin	'68–'85	3.8–24.6	2.1–5.3	0.20–0.79
Inland	'88	2.4–13.0	0.48–2.7	0.06–0.09
L. Erie	'76–'85	15.0–62.0	3.6–26.5	0.53–1.7
	'86	8.6–44.0	2.3–10.0	0.25–0.69
Michigan	'69–'84	1.9–44.0	1.2–14.0	0.14–1.6
Inland	'86	2.0–29.0	1.1–16.0	0.08–0.9

Recent surveys have shown a general improvement in inland populations of bald eagles in Michigan, Wisconsin and Minnesota, and some eagles have re-established nests along the Lake Superior shore and sporadically produce fledged young. In recent years, eagle populations have expanded along the Canadian Lake Erie shoreline, with some breeding success, reflecting the reduced concentrations of organochlorine pesticides in Lake Erie fish and waterfowl. No nesting attempts have been recorded along the Lake Ontario shoreline, however. Nesting rates in the Great Lakes basin are still lagging well behind inland populations. This is indicative of the continuing elevated concentrations of persistent bioaccumulative pollutants in the fish and wildlife on which bald eagles feed in the Great Lakes basin.

The Great Lakes States have issued 709 fish consumption advisories that are currently in effect for waters within their boundaries, including waters of the Great Lakes, Great Lakes tributaries, and waters outside the Great Lakes drainage basin. Pollutants for which these fish advisories exist include 8 of the 28 bioaccumulative chemicals of concern identified in the proposed Guidance. If a potential local health threat exists due to the consumption of sport-caught fish, a State may choose to issue warnings or provide guidance on the quantity and type of contaminated fish which may be consumed. The Great Lakes States in general issue fish contaminant advisories which are based on a system incorporating and weighing such factors as the type of contaminants found in Great Lakes fish flesh, contaminant levels in fish of various sizes and species, the typical consumption rates of sport-fishers, an evaluation of the human health risks due to potential impacts. Fish advisories in the Great Lakes system are discussed further in section II.G.11 below.

B. Great Lakes Water Quality Agreement

1. History of the Great Lakes Water Quality Agreement

The concept of an ecosystem approach to the management of the Great Lakes evolved from the better understanding of how environmental damage has resulted from human use of the natural resources of the Great Lakes System. The research, monitoring and regulatory programs of the United States and Canada illustrate the connections between the use of land, air and water resources and the need to consider the impact of pollutants on the entire Great Lakes Basin Ecosystem. Because of mutual concerns about the protection and use of shared waters, the governments of the United States and Canada have created institutions to foster the joint environmental management of the Great Lakes.

a. *The Boundary Waters Treaty of 1909.* In 1905, the International Waterways Commission was created to advise the governments of the United States and Canada on water levels and flows in the Great Lakes, especially in relation to the generation of electricity by hydropower. However, the Commission's limited advisory powers proved inadequate for problems related to pollution and environmental management. The Boundary Waters Treaty, signed in 1909, provided for the creation of the International Joint Commission (IJC), with the authority to resolve disputes over the use of water resources that crossed the international boundary of the two countries. Since then, most of the IJC's actions have been devoted to regulating water flows, carrying out studies requested by the United States and Canadian governments, and advising the governments regarding pollution-related problems.

Water pollution was one of the first problems referred to the IJC for study in 1912. The IJC concluded in 1919 that water quality problems in the Great Lakes System were of a serious nature and required further pollution control on the part of both countries to resolve. While no new treaty agreement was signed, the United States and Canada each subsequently established water pollution control programs covering a range of activities. Additional studies in the 1940s led the IJC to advocate establishing narrative water quality objectives for the Great Lakes and the creation of technical advisory boards to monitor Great Lakes water quality.

During the 1950s and 1960s, problems on the Great Lakes reached a critical juncture. In 1964, the IJC began a new reference study on pollution in the Lower Lakes. The 1970 reference study report identified excessive phosphorus loadings as the principal cause of eutrophication and proposed system-wide efforts to reduce phosphorus loadings from all sources. The IJC also

urged the United States and Canadian governments to establish uniform effluent limits for all industries and municipal treatment systems in the Great Lakes System. The conclusions of the reference study prompted the United States and Canada to negotiate a new, comprehensive agreement on the environmental management of the Great Lakes in the 1972 Great Lakes Water Quality Agreement.

b. *The 1972 Great Lakes Water Quality Agreement.* The Great Lakes Water Quality Agreement, signed by the United States and Canadian Governments in 1972, established common water quality objectives for the Great Lakes System. Despite complex jurisdictional problems, the basic premise of the 1972 Agreement was that binational management of the Great Lakes by the United States and Canada could effectively protect the Lakes from further adverse effects of pollution. The 1972 Agreement addressed overall pollution and water deterioration in the five lakes, with an emphasis on controlling excessive nutrient loadings. Each country agreed to implement pollution control actions within its own statutory framework in order to fulfill the requirements of the binational agreement. The chief objective was the reduction of phosphorus levels to no more than 1 ppm in discharges from large municipal sewage treatment plants into Lakes Erie and Ontario. New limits were also placed on industrial discharges. Other objectives of this process included the elimination of oil, visible solid wastes and other nuisance conditions. Both countries established Great Lakes research programs, along with programs for cooperative and separate efforts. The 1972 Agreement also contained commitments for joint international surveillance and monitoring programs, coordinated through the regional office of the IJC. These programs focused on freshwater chemistry and reporting the concentrations of ambient pollutants.

In 1977, the Parties assessed the progress in meeting the binational objectives, and determined that total discharge of nutrients into the Lakes had been noticeably reduced. Man-made eutrophication, bacterial contamination and the more obvious nuisance conditions in rivers and nearshore waters had declined. However, new environmental problems involving toxic chemicals were identified through the Great Lakes research programs and the joint United States and Canadian surveillance and monitoring programs. Additionally, an Upper Lakes study concluded that phosphorus objectives should be set for Lakes Huron, Michigan and Superior.

c. *The 1978 Great Lakes Water Quality Agreement.* In 1978, the United States and Canada signed revisions to the Great Lakes Water Quality Agreement that preserved the basic features of the preceding 1972 Agreement while building on its achievements. Like its predecessor, the 1978 Agreement called for establishing common water quality objectives, improving pollution control throughout the System, and continued monitoring by the IJC. The Agreement shifted the focus from solely the control of nutrients to include the control of toxic substances, calling for the virtual elimination of the discharge of persistent toxic chemicals. Persistent toxic chemicals which bioaccumulate can be particularly hazardous to aquatic life, wildlife, and humans. To further improve pollution control, the 1978 Agreement also set target loadings for phosphorus in each Lake.

In recognition of the need to develop an integrated ecological approach, and in contrast to the previous Agreement which called for the protection of the waters of the Great Lakes, the Parties to the 1978 Agreement expanded the area of focus to the Great Lakes Basin Ecosystem, calling for the restoration and maintenance of the chemical, physical and biological integrity of the waters of the Great Lakes Basin Ecosystem. The Great Lakes Basin Ecosystem is defined as the interacting components of air, land, water and living organisms, including humans, within the drainage basin of the St. Lawrence River at or upstream from the point at which this river becomes the international boundary between Canada and the United States (Article I).

d. *The 1987 Amendments to the Great Lakes Water Quality Agreement.* Article X of the 1978 Great Lakes Water Quality Agreement (GLWQA) required the United States and Canada to conduct a comprehensive review of the Agreement following each third biennial report of the IJC. Following independent reviews in 1987, the United States and Canada mutually agreed to initiate joint negotiations to revise the GLWQA. The negotiations centered on the advancements made in science and technology since 1978, and the need to clarify the roles of the two governments and the IJC. The primary terms of the current GLWQA are discussed in section B.2, below.

2. Major Provisions of the Great Lakes Water Quality Agreement

The goal of the current Great Lakes Water Quality Agreement is to restore and maintain the chemical, physical and biological integrity of the waters of the Great Lakes Basin Ecosystem. To achieve this purpose, the United States and Canada, as Parties to the Agreement, committed to using maximum efforts to develop programs, practices and technologies necessary to gain a better understanding of the Great Lakes Basin Ecosystem, and to eliminate or reduce to the maximum extent practicable the discharge of pollutants into the Great Lakes System. Consistent with the provisions of the GLWQA, it is the stated policy of the Parties that:

a. The discharge of toxic substances in toxic amounts be prohibited;

b. The discharge of persistent toxic substances be virtually eliminated; and

c. Coordinated planning processes and management practices be developed and implemented by each jurisdiction to ensure adequate control of all sources of pollutants.

The GLWQA contains both narrative and numerical objectives for the protection of the waters of the Great Lakes System. The General Objectives in Article III are narrative statements consistent with those in effect in all States, which provide that the waters of the Great Lakes System should be free from substances that, for example, interfere with beneficial uses, or produce conditions that are toxic or harmful to human, animal or aquatic life.

Article IV, Annex I contains narrative and numerical pollutant specific objectives that represent the minimum levels of water quality desired in the waters of the Great Lakes System. They are not intended to preclude the establishment of more stringent requirements on the part of either the Parties to the Agreement, or the States or Provinces, and are regarded as interim objectives which the Parties intend will be revised and supplemented over time. In areas where the General or Specific Objectives of the Agreement are not being met due to human activity, the United States and Canada agreed to identify and work toward the elimination of Areas of Concern, Critical Pollutants, and Point Source Impact Zones pursuant to Annex 2.

Article V sets forth provisions for water quality standards, other regulatory requirements and research. Water quality standards and other regulatory requirements of the two governments are to be consistent with the achievement of the General and Specific Objectives. The United States and Canada also agreed to use their best efforts to ensure that water quality standards and other regulatory

requirements of the State and Provincial Governments are similarly consistent with the achievement of these Objectives and to establish research priorities for the Great Lakes in accordance with Annex 17.

Article VI provides that the United States and Canada, in cooperation with State and Provincial Governments, will continue to develop and implement programs and other measures to fulfill the purpose and objectives of the Agreement. Seventeen problem areas are specifically identified, including pollution from municipal and industrial sources, eutrophication, shipping and dredging activities, airborne toxics and remediation activities.

Article VII outlines the powers, responsibilities, and functions of the IJC. Article VIII provides for the establishment of the Great Lakes Water Quality Board and Science Advisory Board to help the IJC perform its functions under the Agreement. Articles IX through XV outline further roles and responsibilities for the IJC, United States and Canadian Governments, and State and Provincial Governments.

Seventeen Annexes to the Agreement contain additional provisions adopted by the United States and Canada. Annex 1 provides specific numerical and narrative objectives for identified chemical, physical, microbiological and radiological conditions. These Objectives to protect the recognized most sensitive use in all waters of the Great Lakes were based on information available at the time of adoption on cause-effect relationships between pollutants and receptors. Additional, specific ecosystem objectives and indicators were adopted for Lake Superior. Ecosystem objectives and indicators will also be developed in the future for Lakes Erie, Huron, Michigan and Ontario. Annex 2 provides for the development and implementation of Remedial Action Plans (RAPs) and Lakewide Management Plans (LaMPs) to address pollution problems associated with 14 identified use impairments in nearshore and open lake waters. The development of RAPs and LaMPs pursuant to this Annex is discussed further in sections I.G.3. and I.G.4. of the preamble below. The provisions of Annex 3 seek to minimize eutrophication problems and prevent degradation with regard to phosphorus in the boundary waters of the Great Lakes System by setting phosphorus load reduction targets. The achievement of these load reduction targets was discussed in section I.A.4.a. above. The remaining Annexes address a wide range of issues including discharges of pollutants from vessels; pollution from shipping sources; dredging; discharges from onshore and offshore facilities; joint contingency planning; hazardous polluting substances; surveillance and monitoring; persistent toxic substances; pollution from non-point sources; contaminated sediment; airborne toxic substances; pollution from contaminated groundwater; and research and development activities.

The United States and Canada meet twice each year to discuss the state of the Lakes and report to the public regularly on the progress of their Great Lakes cleanup efforts. Pursuant to the Agreement, the governments complete technical and progress reports by specified schedules and submit them to the IJC for evaluation and comment.

3. Implementation of the Great Lakes Water Quality Agreement

a. *The International Joint Commission.* The International Joint Commission (IJC) was established by the Boundary Waters Treaty of 1909, and is composed of six Commissioners, three each appointed by the Prime Minister of Canada and the President of the United States. The IJC does not function as a separate national delegation, but as a single body seeking common solutions to the joint interests of the two countries. All Commissioners are expected to act independently of their respective national concerns.

The IJC has three primary responsibilities for the Great Lakes outlined under the original 1909 Treaty: The limited authority to approve applications for the use, obstruction or diversion of boundary waters on either side of the border that would affect the natural level or flow of either side; to conduct studies of specific problems under request from the United States and Canadian Governments; and to arbitrate specific disputes which may arise between the two governments in relation to boundary waters. Upon approval of both Parties, any matters of difference may be referred to the IJC for a final decision.

In addition to these specific powers proscribed to the IJC under the 1909 Treaty, the IJC monitors progress in achieving the goals of the Great Lakes Water Quality Agreement. Two standing advisory boards, the Water Quality Board and the Science Advisory Board, assist in collecting, analyzing and distributing data, and coordinating the implementation of approved actions between the cooperating governmental agencies.

The Water Quality Board is the principal advisor to the IJC and consists mainly of senior staff from the Federal, State and Provincial control agencies selected equally from both countries. The Water Quality Board is responsible for promoting the coordination of Great Lakes programs among the different levels of government and advising the Commissioners on major issues. The Science Advisory Board consists primarily of government and academic experts who advise the Water Quality Board and the IJC on scientific findings and research needs. Both have special committees, task forces and work groups to address specific issues.

b. *Provisions for Consultation and Review.* Under Article IV and Annex I, the Parties committed to the development of Specific Objectives designed to protect the most sensitive use in the Great Lakes waters. These standards, referred to as "Specific Objectives" under the Agreement, were intended by the United States and Canada to represent "the minimum levels of water quality desired in the boundary waters of the Great Lakes System." A number of Specific Objectives have been developed jointly by the United States and Canada, including narrative and numeric criteria for persistent toxic substances, non-persistent toxic substances, and other conventional pollutants. The Agreement, however, recognizes that consistent with the policy of virtual elimination of persistent toxic pollutants set forth in the Agreement, these Specific Objectives should be recognized only as "interim measures."

The Agreement requires the Parties, along with State and Provincial governments, to consult and, as necessary, establish additional Specific Objectives under Annex 1 or modify existing ones. Article X of the GLWQA provides for the modification of existing Objectives and the adoption of new Objectives, the modification or improvement of programs and joint measures, and the amendment of the Agreement or any of its Annexes. Article X also requires the Parties to conduct a comprehensive review of the operation and effectiveness of the Agreement and to evaluate progress in achieving its goals.

c. *Status of Negotiations With Canada on Revising the Specific Objectives.* The United States/Canada Binational Operations Committee (BOC) is currently responsible for developing modifications to the Objectives in Annex 1. The United States and Canada, through the BOC, have agreed to pursue common water quality criteria, methodologies and implementation procedures for the waters of the Great Lakes System. EPA intends to submit the numeric criteria, methodologies, and implementation procedures contained

in the proposed Guidance as the basis for the United States' proposal to modify the GLWQA pursuant to Article X.

C. Governors' Toxics Agreement

In 1986, the Governors of the eight Great Lakes States signed the Great Lakes Toxic Substances Control Agreement (Governors' Agreement), pledging the States' cooperation in studying, managing and monitoring the Great Lakes as an integrated ecosystem. The purpose of the Agreement is to establish a framework for coordinated regional action in controlling toxic substances entering the Great Lakes System; to further the understanding and control of toxic contaminants; and to develop common goals, management practices and control strategies for toxics to ensure a cleaner and healthier Great Lakes Basin Ecosystem.

The Governors' Agreement identified six principles to guide State actions to address pollution in the Great Lakes. First, the Governors agreed to manage the water resources of the Great Lakes based on a recognition of the economic and environmental importance of this natural resource. Second, the Governors committed to managing the Great Lakes as an integrated ecosystem, recognizing that the water resources of the ecosystem transcend political boundaries. Third, the signatory States concurred that the problem of persistent toxic substances constitutes the foremost environmental issue confronting the Great Lakes. Fourth, the Governors committed to continue reducing toxics in the Great Lakes System to the maximum extent possible consistent with the Federal Clean Water Act goal of prohibiting the discharge of toxic pollutants in toxic amounts as well as the Great Lakes Water Quality Agreement's goal of virtual elimination of the discharge of all persistent toxic substances. Fifth, the States committed to cooperating among themselves and with local and State agencies, regional groups, the Federal government, the IJC and the public in the study, monitoring and management of the Great Lakes. Finally, the States agreed to work cooperatively to improve the region's information retrieval and technical analysis capabilities, recognizing that compatible data bases are key to the development of effective regulations and the control of toxic substances in the Great Lakes System.

The States also agreed that maintaining the water quality of the Great Lakes and stimulating economic growth are complementary goals. By maintaining and improving the quality of Great Lakes waters, the States indicated that they would sustain water supply systems and commercial, manufacturing and recreation industries, while creating new economic development opportunities. Therefore, the signatory States agreed to maintain a high standard of water quality when establishing regulatory standards, and to allow new or increased discharges that have the potential to lower water quality only when no prudent or feasible alternative to such discharge exists.

The signatory parties also agreed that the permitting process is the best means now available to regulatory agencies and dischargers to control the releases of toxic substances into the Great Lakes System and that discharges, emissions or releases of toxic substances will be controlled by a regulatory permit process in order to reduce or eliminate the negative effects of toxics on human health and the environment.

To implement the goals of the Governors' Agreement, the signatory States directed their environmental administrators to jointly develop an agreement for coordinating the control of toxic releases and achieving greater uniformity of regulations governing such releases within the Great Lakes System. This coordinated effort between the Great Lakes States contributed to the development of the Great Lakes Water Quality Initiative.

Finally, the Governors of the signatory States committed to coordinate the implementation of this agreement and to review the progress made towards its implementation on an annual basis. As part of its role in implementing this agreement, each jurisdiction agreed to develop a management plan appropriate to its own political and regulatory system. The environmental administrators of each State review these plans annually.

D. Great Lakes Water Quality Initiative

1. Formation of Great Lakes Water Quality Initiative

In June 1989, EPA's Region V initiated the effort known as the Great Lakes Water Quality Initiative. This effort was intended to provide a forum for State and EPA development of uniform water quality criteria and implementing procedures for the Great Lakes basin. The participants planned to use the results of this effort as a basis for revising State water quality standards during the next triennial review period required by section 303(c) of the CWA and to negotiate revised Specific Objectives and related protocols with Canada under the GLWQA.

Three committees were formed under the GLWQI. A Steering Committee, consisting of directors of water programs from EPA's national and regional offices and the Great Lakes States' environmental agencies (as co-regulators of CWA water quality programs), discussed policy, scientific, and technical issues and directed the work of the Technical Work Group. The Technical Work Group (consisting of technical staff from the Great Lakes States' environmental agencies, EPA, the U.S. Fish and Wildlife Service and the U.S. National Park Service) prepared proposals for submission to the Steering Committee. The Public Participation Group (consisting of representatives from environmental groups, municipalities, industry, and academia) observed the deliberations of the other two groups, advised them of the public's concerns, and kept its various constituencies apprised of GLWQI activities.

Of particular concern to the Steering Committee were those pollutants which persist throughout the Great Lakes ecosystem and have a propensity to bioaccumulate in the food chain, thereby exhibiting or having the potential to exhibit systemwide impacts. As discussed in section I.A. of this preamble above, although levels of certain pollutants with systemwide impacts have significantly declined in recent years, the rate of decline has diminished. Fish tissue concentrations of these pollutants have leveled off in some cases, and may be approaching equilibrium at concentrations well above levels of concern as defined by water quality criteria calculations. Projections indicate that given the current rate of pollutant loadings to the Great Lakes System it will take many years for fish tissue concentrations of these highly bioaccumulative pollutants to reach concentrations which allow unrestricted consumption of Great Lakes fish. State and EPA scientists believe that this is the result of the unique properties of the Great Lakes ecosystem.

The Steering Committee believed that further reductions in loadings of such pollutants from all sources should be pursued. Furthermore, the Steering Committee was concerned that action be taken to ensure that problems would not develop in the future with pollutants which show a propensity to bioaccumulate and persist in the Great Lakes ecosystem, thereby potentially causing impairment of beneficial uses. Therefore, the Steering Committee initiated action by EPA and State staff on the Technical Work Group to define the persistent and bioaccumulative pollutants that warrant additional controls, and to develop proposed

additional control approaches for those pollutants.

To define the pollutants that warrant additional controls, the Technical Work Group considered two factors for ranking and selection purposes: Persistence and bioaccumulation.

—The persistence of a pollutant was recognized as an important factor for the reasons discussed in section I.A of this preamble. The Technical Work Group believed, however, that research to date does not suggest a scientific approach that would allow a systematic ranking of pollutants in terms of their persistence in the Great Lakes system. Persistence depends on the cumulative effect of several fate and effect processes, such as volatility, anaerobic degradation, hydrolysis, and photolysis. The Technical Work Group believed that systematic data were generally not available for these individual processes as they function in the Great Lakes system. In addition, the Technical Work Group believed that data are not systematically available concerning the cumulative effect of individual fate and effect processes on specific pollutants in the Great Lakes ecosystem under field conditions, or under laboratory conditions which have been field correlated and verified.

—Bioaccumulation was recognized as an important factor because of its ability to magnify the exposure of humans and wildlife to toxic pollutants. As discussed further in sections II.G and IV of this preamble, methods and data exist to allow calculation of bioaccumulation factors (BAFs) for the 138 pollutants of initial focus in the Great Lakes Water Quality Initiative. The methodology for developing BAFs provide for use of data collected under field conditions or data collected under laboratory conditions which have been field correlated and verified. BAFs measure the uptake and retention of substances by organisms from the water and the food chain, and are expressed as the ratio of a substance's concentration in tissue of aquatic organisms to its concentration in ambient water.

The Technical Work Group proposed utilizing a bioaccumulation factor methodology which incorporates metabolism and other physicochemical properties as a mechanism by which to identify those pollutants which warrant additional controls. The Steering Committee agreed, and selected a bioaccumulation factor (BAF) of 1000 as an indicator of a pollutant's ability to be highly bioaccumulative, and proposed designating such pollutants as bioaccumulative chemicals of concern (BCCs). The selection of the BAF level of 1000 is discussed further in section II.G below. Pollutants with a BAF greater than 1000 were believed by the Steering Committee to have a high potential to be found throughout the food chain of the Great Lakes ecosystem and therefore to have the potential to cause a significant risk to the health of aquatic life, wildlife and humans which inhabit the Great Lakes Basin. The Steering Committee recognized that metabolism, molecular size and other physicochemical properties might effect bioaccumulation. Therefore, the BAF methodology being proposed in appendix F of part 132 includes provisions for States and Tribes to consider these properties in developing BAFs.

EPA and the Technical Work Group recognize that using bioaccumulation alone as a ranking and selection factor is more conservative than considering both persistence and bioaccumulation together, since there may be highly bioaccumulative pollutants that do not persist long in the Great Lakes Basin Ecosystem. The proposal to establish additional controls on chemicals with a BAF over 1000 ensures that all pollutants with both properties, persistence and bioaccumulation, will be controlled.

EPA believes the selection of BCCs for special attention in the Guidance is in conformance with the Great Lakes Water Quality Agreement, which calls for a focus on persistent toxic pollutants. Article II of the Agreement states that it is the policy of the parties to the Agreement that the discharge of any or all persistent toxic substances be virtually eliminated, where persistent toxic substances are defined in Annex 12 of the Agreement as any toxic substance with a half-life in water of greater than eight weeks. As discussed above, the Technical Work Group was unable to develop systematic quantitative information, including overall half lives, on persistence in the Great Lakes Basin Ecosystem. Nevertheless, in the professional judgment of EPA scientists, the BCCs identified in Part A of Table 6 of the proposed Guidance are relatively persistent in aquatic organisms and highly bioaccumulative. Therefore, they would most likely qualify as persistent toxic substances under the Agreement.

EPA invites comment on the approach described above for selecting pollutants for special attention in the Great Lakes System. In particular, EPA would like comments on the use of bioaccumulation factors as the sole quantitative factor to evaluate pollutants for special attention; comments on whether data concerning other factors that reflect persistence as well as, or instead of, bioaccumulation should be used to select pollutants; and if so, any supporting data concerning overall actual or estimated persistence in the Great Lakes Basin Ecosystem, and comments on what overall half life should be used to select pollutants. Furthermore, EPA would be interested in any data showing that a specific BCC does not persist in the Great Lakes Basin Ecosystem for at least the 8-week half life specified in the Great Lakes Water Quality Agreement, as measured by a suitable method of estimating overall half lives. EPA invites comment on whether such data should be used as the basis for a possible exclusion of short-lived pollutants from the definition of BCC.

The Steering Committee judged that every reasonable effort should be made to reduce loadings of all BCCs. For example, the Steering Committee believed mixing zones should be eliminated for BCCs as a way to reduce mass loadings to the Great Lakes. In particular, the Steering Committee was concerned that mixing zones on large tributaries not be used to allow significant mass loadings of BCCs to the Lakes.

The Steering Committee believed that new loadings of pollutants with a high potential to bioaccumulate should be severely restricted. Pollution prevention approaches, which eliminate the generation of pollutants at the source are inherently less costly than removing pollutants once they have entered the environment. Accordingly, the Steering Committee endorsed more stringent antidegradation procedures for pollutants with a high potential to bioaccumulate. In addition, since many of these pollutants are problematic even when discharged below the level of detection, due to their bioaccumulation in the food chain to unsafe levels, the Steering Committee believed dischargers of these pollutants should conduct minimization programs to eliminate the internal sources of these pollutants. Furthermore, the Steering Committee reasoned that bioaccumulative chemicals are those for which surface water pathways are likely to be major contributors to total human exposure, and therefore the non-cancer human health criteria should be adjusted through use of a relative source contribution (RSC) factor of 80 percent.

EPA is including the Steering Committee's special regulatory provisions for mixing zones,

antidegradation, minimization programs, and human health criteria development for BCCs in the proposed Guidance. The special regulatory provisions include portions of the human health criteria development methodologies in appendix C, the antidegradation policy in appendix E, and procedure 3 (total maximum daily loads) and procedure 8 (WQBELs below the levels of detection) in appendix F. Discussions of these provisions are provided in sections V, VII, VIII.E, and VIII.H of this preamble. EPA believes that the special requirements developed by the Steering Committee are a reasonable approach, although not necessarily the only reasonable approach to address the issue of persistent bioaccumulative pollutants in the Great Lakes System, for the following reasons:

—Persistence of toxic pollutants is a major concern in an aquatic system like the Great Lakes, for the reasons discussed in section I.A above. It is especially problematic for chemicals that are highly bioaccumulative, because the most important exposure pathway for humans and wildlife in the Great Lakes System is consumption of fish and other aquatic organisms. Persistent bioaccumulative chemicals will result in high exposures to humans and wildlife for a long time to come.

—The proposed human health and wildlife criteria may not be sufficiently protective for persistent bioaccumulative chemicals. The proposed criteria are derived using available data and assumptions regarding data gaps. Despite the inherently conservative nature of the assumptions used when data gaps occur, it is possible that in some cases the criteria may not be sufficiently stringent. Considering the conservative elements of the criteria development methodologies, the risk of criteria not being sufficiently stringent is acceptable with respect to pollutants that are not persistent in the environment, since the resulting unacceptable impacts will be relatively temporary in duration. For persistent bioaccumulative pollutants, however, the risk may not be acceptable in the Great Lakes Basin Ecosystem where recycling of pollutants in a relatively closed system may result in unacceptable impacts that are long term in duration, and make future cleanup actions more difficult, costly, and time consuming. Accordingly, additional controls intended to prevent concentrations of persistent bioaccumulative pollutants from increasing to the level of criteria concentrations in Great Lakes waters are reasonable.

—Both options for development of total maximum daily loads proposed in the Guidance envision predominant use of a simple, steady-state mass balance approach. A mass balance approach is a method used to approximate the mass of pollutants within a water body. This approach assumes that the input of mass into the system (e.g., through point and nonpoint source loadings, atmospheric deposition, groundwater seepage) equals the loss of mass from the system plus any losses due to transformation of mass within the system. Because both options assume a simple steady state, it is assumed that no mass can be accumulated in the system. This provides for a first approximation of allowable loading allocations. For persistent bioaccumulative pollutants, however, this approximation will likely not be accurate. As discussed in section I.A of this preamble above, there are significant interactive physical, chemical, and biological processes that affect the long-term behavior of persistent bioaccumulative pollutants in the Great Lakes system, resulting in fairly common occurrences where such pollutants do accumulate in various compartments in the system. The proposed TMDL procedures provide for subsequent monitoring to identify any shortcomings in the control approach and provide for appropriate revisions. For persistent bioaccumulative pollutants, however, this approach may present a significant risk of allowing the pollutants to concentrate in the ecosystem above ambient criteria levels before the control approach can be revised and cleanup actions take full effect. EPA believes the costs of future remediation actions to address BCCs would be significantly more expensive than efforts to control the BCCs before they enter the environment. Accordingly, additional controls intended to prevent concentrations of persistent bioaccumulative pollutants from increasing to the level of criteria concentrations in Great Lakes waters are reasonable.

—The proposed Guidance contains no regulatory text concerning the additivity of the toxic effects of pollutants, although the preamble discusses several approaches that EPA may decide to include in the final rule. To the extent that the final rule contains no provisions that directly address risks related to additivity, or contains provisions that directly address some but not all aspects of additivity, additional controls intended to prevent concentrations of persistent bioaccumulative pollutants from increasing to the level of criteria concentrations in Great Lakes waters are reasonable to account for their possible additive effects. For persistent bioaccumulative pollutants any additional effects would be more difficult to overcome because of the longer times required to identify problems, establish controls, and implement the controls, and for the ecosystem to respond, ultimately restoring beneficial uses.

The proposed Guidance calling for special, more restrictive measures for BCCs which could cause lakewide impairments of beneficial uses is consistent with the Great Lakes Water Quality Agreement goal of virtual elimination of toxics, the recommendation of the Great Lakes Governors Toxic Substances Control Agreement calling for the continued reduction of toxics in the Great Lakes System to the maximum extent possible, and the Clean Water Act goal of fishable waters. The elimination of mixing zones for BCCs in the Great Lakes system is consistent with current National regulations and guidance and the Great Lakes Water Quality Agreement. EPA regulations provide that States may, at their discretion, provide for mixing zones as part of their State water quality standards. EPA's 1991 guidance document, "Technical Support Document for Water Quality-based Toxics Control," recommends that States provide a definitive statement in their water quality standards as to whether or not mixing zones are allowed and states that as our understanding of pollutant impacts on ecological systems evolves, there may be cases identified where mixing zones are not appropriate and should not be allowed. The Great Lakes Water Quality Agreement supports the elimination of point source impact zones (mixing zones) for toxic substances (GLWQA at Annex 2 Paragraph 2.(d)).

EPA invites comments on these issues. EPA recognizes that there may be other reasonable approaches to protect the Great Lakes ecosystem from the effects of persistent bioaccumulative pollutants. For example, it may be possible to devise a comprehensive system of monitoring and special NPDES permit requirements to guard against the buildup of such chemicals past the point where the regulatory control process can prevent levels from

exceeding criteria in the future because of interactive processes and effects in the relatively closed Great Lakes Basin Ecosystem. EPA invites comments on such possible alternatives, how effective they may be in addressing the types of problems discussed above, and how easily they may be implemented.

Further discussion of the definition of BCCs, the selection process for the BCCs listed in Parts A and B of Table 6 of part 132 of the proposed Guidance, and an invitation for comments on specific issues is found in section II.G. below. A more detailed discussion of the special regulatory requirements imposed on BCCs is found in sections II.G, VII, VIII.C, and VIII.E of this preamble below.

2. Great Lakes Critical Programs Act of 1990

The above efforts by the Great Lakes Water Quality Initiative were well underway in 1990 when Congress passed the Great Lakes Critical Programs Act (CPA). In developing this legislation, Congress praised the ongoing efforts of the Initiative to develop guidance on minimum requirements for the Great Lakes States' water quality programs. 136 Cong. Rec. S. 15620, 15623 (Oct. 17, 1990) (Remarks of Senator Levin). (See also discussion of legislative history in section II.E.1.c. below.) Congress amended section 118 of the Clean Water Act through the Great Lakes Critical Programs Act of 1990 (CPA) (Public Law 101–596, Nov. 16, 1990). The general purpose of these amendments was to improve the effectiveness of EPA's existing programs in the Great Lakes by identifying key treaty agreements between the United States and Canada in the Great Lakes Water Quality Agreement, imposing statutory deadlines for the implementation of these key activities, and increasing federal resources for program operations in the Great Lakes System. (*Id.*).

Section 101 of the CPA (Clean Water Act section 118(c)(2)) requires EPA to publish proposed water quality guidance for the Great Lakes System which conforms with the objectives and provisions of the GLWQA and is no less restrictive than provisions of the Clean Water Act and national water quality criteria and guidance. The guidance must specify minimum requirements for the waters in the Great Lakes System in three areas:

a. Water quality standards (including numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life and wildlife);

b. Antidegradation policies; and

c. Implementation procedures.

The CPA amendments require the Great Lakes States to adopt water quality standards, antidegradation policies and implementation procedures for waters within the Great Lakes System which are consistent with the final guidance. If a State fails to adopt consistent provisions within two years of EPA's publication of the final guidance, EPA is required to promulgate any necessary requirements for the State within that two-year period. The proposed procedure for State and Tribal adoption of these provisions is set forth in section II below.

The statutory requirements to develop guidance for the Great Lakes were intended to codify the ongoing efforts of EPA and the eight Great Lakes States under the Great Lakes Water Quality Initiative. 136 Cong. Rec. S. 15620, 15624 (Oct. 17, 1990) (remarks of Sen. Levin and Sen. Glenn) Congress recognized that a primary goal of the Great Lakes Water Quality Initiative was to identify, through a regional dialogue, minimum guidelines to reduce disparities among water quality controls in the Great Lakes. Congress intended that the Great Lakes Guidance would similarly move the Great Lakes States toward a more consistent, region-wide implementation of the GLWQA by addressing "the topics already under discussion in the region: Minimum water quality standards for selected pollutants, antidegradation policies and implementation procedures." (*Id.*) As discussed further in section II.E.1.c. below, the establishment of a more uniform control of water pollution in the Great Lakes System was one of the most important goals of this legislation.

In addition to the requirement to develop the Great Lakes Water Quality Guidance in the proposed Guidance, the 1990 amendments to section 118 specified requirements for several other ongoing EPA programs in the Great Lakes. For example, the amendments also included requirements or deadlines for research on contaminated sediments; development of numerical sediment criteria; development of a Lakewide Management Plan for Lake Michigan and Remedial Action Plans for Areas of Concern; development of management plans for confined disposal facilities; and the assessment of spills of oil and hazardous materials in the Great Lakes. These, as well as other, separate EPA and State programs to address water quality problems in the Great Lakes System, are addressed in section G below.

3. Process After the CPA

Following the passage of the Great Lakes Critical Programs Act of 1990, EPA and the eight Great Lakes States intensified efforts on the Great Lakes Water Quality Guidance. On December 6, 1991, the GLWQI Steering Committee recommended unanimously that EPA publish the proposed Great Lakes Guidance as approved by the Steering Committee in the **Federal Register** for public comment. The agreement that the Great Lakes Guidance was ready for public notice did not represent an endorsement by every State of all of the specific proposals. Each State indicated its intention to fully review the proposed Great Lakes Water Quality Guidance and submit specific comments during the public comment period.

EPA has generally used the December 6, 1991, Steering Committee proposal as the basis for the proposed Guidance. However, the proposed rule contains a number of substantive clarifications, additions, and modifications to the Guidance endorsed by the GLWQI Steering Committee to reflect statutory and regulatory requirements or EPA policy considerations. In addition, EPA has reorganized and modified the Steering Committee proposal for publication in the **Federal Register**, and added proposed regulatory requirements and procedures for State and Tribal adoption of the final Guidance. All sections of the Guidance approved by the Steering Committee on December 6, 1991 are either incorporated in the proposed Guidance or discussed in the preamble.

The Great Lakes States requested the opportunity to provide EPA with their views on the public comments submitted on the proposed Guidance. Accordingly, following the close of the public comment period, EPA intends to compile the public comments and hold an open public meeting for the purpose of receiving the views of both the Great Lakes States and other members of the public on the written comments. The date, time and location of the public meeting will be published in the **Federal Register** and a summary of the meeting will be included in the public docket.

E. Elements of the Guidance

1. Water Quality Criteria for the Protection of Aquatic Life

The Guidance proposes numeric criteria to protect aquatic life for 16 pollutants, and a two-tiered methodology to derive criteria and values for additional pollutants discharged to the Great Lakes System. Aquatic life criteria are derived to establish ambient concentrations for pollutants, which, if not exceeded in the Great Lakes System, will protect fish.

benthic organisms, and other aquatic life from impacts due to that pollutant. EPA is proposing an acute criterion and a chronic criterion for most of the 16 pollutants specifically addressed today. An acute criterion indicates the maximum concentration which, if not exceeded, will protect organisms in the Great Lakes System from short duration exposures. They apply in all parts of the Great Lakes System, including areas near points of discharge where physical mixing of discharge water and receiving water occurs. A chronic criterion indicates the maximum concentration which, if not exceeded, will protect organisms in the Great Lakes System from long duration exposures. Chronic criteria do not generally apply to areas near discharge points where mixing occurs. The acute criteria proposed are set at a higher concentration than chronic criteria.

Aquatic life criteria for each chemical are primarily based on laboratory toxicity data for a variety of aquatic species (e.g., fish, benthic invertebrates, plants) which are representative of the species in the environment as a whole. In some cases, the proposed Tier I numeric criteria include more current toxicity data than existing National criteria guidance due to the availability of more recent data. The Great Lakes Water Quality Guidance also proposes a translator procedure (the Tier II methodology) to develop water quality-based effluent limitations for NPDES permits in the absence of the full Tier I data requirements. The Great Lakes States and Tribes are not required or encouraged to use the Tier II methodology to adopt water quality criteria under section 303 of the Clean Water Act. States must use the Tier II methodologies, however, in conjunction with the proposed whole effluent toxicity requirements to implement their existing narrative toxics criteria in the absence of data necessary to derive water quality criteria or numerical effluent limitations under the proposed Tier I methodologies.

The above-mentioned procedures result in two tiers of aquatic life protection and allow the application of the Great Lakes Water Quality Guidance to all pollutants, except those listed in Table 5 of this proposal. Tier I numeric criteria are based on data requirements very similar to those used in current National guidance, i.e., acceptable toxicity data for aquatic species in at least eight families which represent differing habitats and taxonomic groups must exist before a Tier I numeric criterion can be derived. Tier II values are used when the minimum Tier I data requirements are not met, but a value equivalent to a water quality criterion needs to be derived in order to make the permitting and control decisions necessary to address a pollutant discharge. Tier II values can, in certain instances, be based on toxicity data from a single taxonomic family.

2. Water Quality Criteria for the Protection of Human Health

The Guidance proposes numeric criteria to protect human health for 20 pollutants and a methodology to derive cancer and non-cancer human health criteria and values for additional pollutants discharged to the Great Lakes System. Human health criteria are derived to establish ambient concentrations of chemicals which, if not exceeded in the Great Lakes System, will protect individuals from adverse health impacts from that chemical due to consumption of aquatic organisms and water, including incidental water consumption related to recreational activities in the Great Lakes System. For each chemical, chronic criteria are derived to reflect long-term consumption of food and water from the Great Lakes System.

As with the aquatic life criteria procedure, the human health procedure results in two tiers of numeric values: Tier I numeric criteria and Tier II values. For Tier I numeric criteria, dose-response data are derived from human or animal studies which are associated with no observable toxic effect. Studies are evaluated for both carcinogenic and non-carcinogenic effects. Numeric criteria are calculated by integrating an assessment of the relationship between the dose of a chemical and the potential for causing an adverse effect with appropriate exposure assumptions based on data from the Great Lakes System for consumption of fish, bioaccumulation in fish, and consumption of water, to yield an ambient water concentration that is not likely to result in adverse human health effects over the course of a human lifetime.

Under the Tier II procedures, Tier II values will be established for chemicals with an insufficient database to meet Tier I requirements. Tier II values may be established for non-carcinogenic and carcinogenic endpoints depending on the adequacy of data.

The Great Lakes Water Quality Guidance differs from current National water quality guidance by using bioaccumulation factors which account for direct uptake from the waters of the Great Lakes System plus uptake from the food chain. This consideration often results in the development of more stringent criteria. Additionally, a fish consumption rate that is based on data from the Great Lakes area is used in the proposed Guidance. This value is higher than that used in the National guidance. This results in more accurate and protective, although more stringent, criteria that appropriately reflect Great Lakes fish consumption rates.

3. Water Quality Criteria for the Protection of Wildlife

The Guidance proposes numeric criteria to protect Wildlife for four pollutants and a methodology to derive criteria and values for additional pollutants discharged to the Great Lakes System. Wildlife criteria are derived to establish ambient concentrations of chemicals which, if not exceeded, will protect mammals and birds from adverse impacts from that chemical due to consumption of food and/or water from the Great Lakes System. The Great Lakes wildlife criteria are the highest calculated aqueous concentrations of substances which cause no significant reduction in growth, reproduction, viability or usefulness of a population of exposed animals that use Great Lakes System waters for food or drinking over several generations. For most chemicals of concern, piscivorous wildlife species have been identified as most at risk within the Great Lakes System. Based on an analysis of body size and foraging behavior for wildlife in the Great Lakes System, the mink and river otter, and the eagle, osprey, and belted kingfisher have been selected as representative mammalian and avian species for calculating these criteria.

For each chemical, only a chronic criterion is derived in the Great Lakes Water Quality Guidance because adverse effects to wildlife normally occur only over relatively long periods of time through continued periodic exposure to contaminated food and water from the Great Lakes System.

The wildlife procedure results in the same type of two-tier protection as the aquatic life and human health procedures. Tier I numeric criteria are based on dose response data from birds and mammals. Either field studies or laboratory studies serve as sources of data. Tier II values may be based on data from a single taxonomic class, and may come from laboratory studies of more limited scope for mammals. For birds, studies must meet the same requirements as for Tier I.

The development of wildlife criteria procedures within the Great Lakes Water Quality Guidance is a significant addition to current national guidance as EPA has not published a separate wildlife criteria methodology at the National level. Only four numeric

wildlife criteria are being proposed for two major reasons: Field studies from the Great Lakes indicate that the four pollutants for which wildlife criteria are proposed have had the most severe impacts on wildlife within the Great Lakes; and the criteria proposed are the first set of criteria for wildlife that EPA has ever developed. EPA cannot take advantage of an established and peer-reviewed national methodology to develop wildlife criteria as it can for both human health and aquatic life criteria. The Initiative Committees and EPA lacked time and resources to develop additional numeric criteria for wildlife prior to this proposal. The State of Wisconsin had already identified these four chemicals as chemicals of concern for wildlife impacts in their State and completed literature reviews for these four chemicals. These literature reviews were updated as part of the GLWQI effort.

4. Bioaccumulation Factors

The Great Lakes Water Quality Guidance contains a procedure for determining bioaccumulation factors which are used to estimate the intake of chemicals via consumption of fish by wildlife species and humans. The Great Lakes Water Quality Guidance proposes to use bioaccumulation factors in the calculation of wildlife criteria and human health criteria to account for the tendency of organisms to accumulate certain chemicals in their tissues to concentrations many times greater than the concentration of the chemical in the water body. For certain chemicals, this tendency to bioaccumulate becomes more pronounced with every level of the food chain through which the chemical passes. To protect species at all levels of the food chain requires relatively stringent criteria for those chemicals which bioaccumulate in organisms. Bioaccumulation factors are generally higher than the bioconcentration factors currently in use by most States and EPA in deriving water quality criteria to protect human health. This is due to the fact that bioconcentration accounts only for uptake by aquatic organisms directly from water alone, while bioaccumulation factors account for accumulation through the food chain.

The bioaccumulation factor used in the calculation of human health criteria in the Great Lakes Guidance is different from the one used to calculate the wildlife criteria for any given chemical. This is due to the type and form of food eaten by wildlife (whole body), which is different from that typically eaten by people (muscle tissue alone). Since many chemicals of concern tend to bioaccumulate in fat more than other tissues, the bioaccumulation factor used in calculating human health criteria will in many cases be lower than the one used in calculating wildlife criteria. Also, significant differences in the types of species consumed by wildlife versus those consumed by people may also affect the bioaccumulation factor used in calculating human health criteria versus wildlife criteria for the Great Lakes System.

5. Antidegradation

The Great Lakes Guidance antidegradation policy is intended to protect and maintain existing water quality. The concept was developed in the regulatory context as early as 1968 by the Department of Interior and is included in federal regulations (40 CFR 131.12) and reflected in the Clean Water Act. However, specific National guidance on implementation of this concept within the context of current regulatory programs (e.g., NPDES permits) has never been developed, resulting in a myriad of State implementation procedures with various levels of protection.

The Great Lakes Water Quality Guidance proposes detailed antidegradation implementation guidance to ensure that all of the States and Tribes in the Great Lakes System carry out this important water quality concept in a consistent and protective manner. Antidegradation provides three different levels of protection, depending on the water quality in the receiving water body. First, for all water bodies, water quality cannot be degraded below the level protecting existing uses, which are defined as any uses that a water body has actually supported since 1975. If a water body has supported, for example, a fishery at any time since 1975—whether or not the fishery is still in existence—no chemical can be discharged at a level that would impact the water quality needed for a fishery, even if allowing the discharge would be socially and economically important to the community.

Second, if the water body is not an Outstanding National Resource Water (ONRW), but ambient water quality is better than the quality needed for fishable/swimmable uses for any given chemical, then significant increased loadings of that chemical are allowed only if the State or Tribe determines that it is necessary for important social and economic development in the area where the increase is proposed. The Great Lakes Water Quality Guidance antidegradation procedures specify how Great Lakes States or Tribes will determine when a proposed action, such as an NPDES permitted discharge, will result in significant lowering of water quality in the water body, whether it is necessary for that action to significantly lower water quality, and how the socio-economic importance of such an action will be evaluated. In general, NPDES permit conditions for chemicals which bioaccumulate will restrict dischargers to the loadings currently measured in their effluent, unless the discharger demonstrates the need to accommodate important social and economic development.

Third, if a State or Tribe has designated a water body as an Outstanding National Resource Water (ONRW), then no permanent degradation is allowed under any circumstances.

6. Implementation Procedures

In addition to the water quality criteria and antidegradation policies discussed above, the proposed Guidance includes procedures to convert water quality criteria and values into specific controls on sources of pollutants in the Great Lakes System. Various procedures to implement State numeric and narrative water quality criteria are currently contained in EPA regulations and guidance and in individual State water quality standards or NPDES programs authorized under section 402 of the Clean Water Act.

The 1990 amendments to section 118(c)(3) require EPA to publish guidance on minimum implementation procedures for the Great Lakes System. One of the most important goals of this legislation was the establishment of a more uniform level of control of water pollution by the Great Lakes States. Consistent procedures to translate water quality criteria into specific controls on pollutant sources are essential to this goal.

Appendix F of the proposed Guidance specifies minimum requirements for procedures to implement water quality criteria in the following areas:

a. Site-specific modifications to criteria/values (implementation procedure 1 of appendix F to part 132);

b. Variances from water quality standards (implementation procedure 2 of appendix F to part 132);

c. Total maximum daily load/wasteload allocation procedures/mixing zones for point sources (implementation procedure 3 of appendix F to part 132);

d. Additivity (implementation procedure 4 of appendix F to part 132, which is reserved in the proposed Guidance);

e. Reasonable potential to exceed numeric water quality standards

(implementation procedure 5 of appendix F to part 132);

f. Whole effluent toxicity requirements (implementation procedure 6 of appendix F to part 132);

g. Loading limits (implementation procedure 7 of appendix F to part 132);

h. Water quality-based effluent limitations below the levels of detection (implementation procedure 8 of appendix F to part 132); and

i. Compliance schedules (implementation procedure 9 of appendix F to part 132).

F. Science Advisory Board Review

The EPA Science Advisory Board (SAB) was established to provide independent advice to EPA on the scientific and technical aspects of environmental problems and issues. (See Environmental Research, Development and Demonstration Act of 1978, 42 U.S.C. 4365.) EPA submitted the draft proposals developed by the Great Lakes Water Quality Initiative Steering Committee for the aquatic life methodologies, the wildlife methodologies, the human health methodologies, and the bioaccumulation methodology to the SAB for review on January 8, 1992. EPA generally used the Steering Committee proposal as the basis for developing the Great Lakes Water Quality Guidance proposed by EPA. EPA requested SAB review of these draft documents due to their scientific and technical complexity and potential effect on EPA's current National guidance in these areas.

The SAB completed its review of these draft documents on December 16, 1992. A copy of the SAB report (EPA–SAB–EPEC/DWC–93–005) is contained in the public docket of this rulemaking. The report was prepared jointly by the SAB's Great Lakes Water Quality Subcommittee of the Ecological Processes and Effects Committee and the Drinking Water Committee. The SAB commended EPA for the interactions among the States, EPA, the private sector and the scientific community during the development of this proposed Guidance and provided substantial comments on many elements of the submitted draft documents. Some of the questions and comments raised in the SAB review were identified by EPA during the subsequent preparation of the proposed Guidance, and resulted in modifications to the proposed rule. The remaining major issues raised by the SAB have been highlighted by EPA in the appropriate preamble sections to solicit full public review and comment.

G. Other Programs to Protect and Restore the Great Lakes

In addition to the Great Lakes Water Quality Guidance described in the proposed Guidance, the United States is currently implementing several regulatory and voluntary programs to prevent pollutants from being introduced, reduce pollutant loadings currently being discharged, and remediate the adverse effects associated with past pollutant discharges to the Great Lakes System. Several of these programs are described below.

1. Great Lakes Five-Year Strategy

The EPA and 15 Federal, State and Tribal agencies have developed a Five-Year multi-media Strategy to reduce toxic loadings from all sources of pollution in the Great Lakes System ("Protecting the Great Lakes: Our Environmental Goals and How We Plan to Achieve Them," USEPA, April 1992). The goals of this inter-agency Strategy are to:

a. Reduce and virtually eliminate toxic substances in the Great Lakes Basin Ecosystem;

b. Protect and restore habitats vital for support of healthy and diverse communities of plants, fish and wildlife; and

c. Ensure the protection of human health while restoring and maintaining the biological diversity among Great Lakes fish, aquatic life, wildlife and plants.

The Strategy includes specific commitments and activities that will be coordinated among the Federal, State and Tribal agencies to achieve these common environmental goals. For example, elements of the Strategy include: Implementation of the Clean Air Act Amendments to reduce atmospheric deposition of toxics; application of the National Contaminated Sediment Strategy to assess, prevent and remediate contaminated sediments; measures to implement best management practices to control runoffs from such diffuse sources as agriculture, silviculture, mining and construction sites; and the coordinated development of agency and State work plans to target actions on specific pollutants of concern in the Great Lakes System.

2. Great Lakes Pollution Prevention Action Plan

The Pollution Prevention Act of 1990 declares as National policy that pollution prevention is the preferred approach to environmental protection: reducing or eliminating pollution through, for instance, changes in production processes and/or by reducing reliance on environmentally harmful materials. (Pub. L. 101–508, section 6601–6610, 104 Stat. 1388, codified at section 13101–13109 West Supp. 1991). When preventing pollution is not feasible, recycling in an environmentally safe manner is the next preferred option, followed by treatment. Disposal or other release into the environment should be the management option of last resort, and should only be done in an environmentally protective manner.

Consistent with the goals of the Pollution Prevention Act, EPA developed the Great Lakes Pollution Prevention Action Plan (April, 1991). The Action Plan highlights how EPA, in partnership with the States, will incorporate pollution prevention into actions to reduce the use and release of toxic substances in the Great Lakes basin. These activities are designed to complement efforts already underway at the State and Federal levels.

The Action Plan has two distinct components. First, it includes new initiatives designed to promote innovative pollution prevention practices throughout the basin. Second, it involves reorienting and refocusing existing activities, such as enforcement actions, to ensure that pollution prevention is an integral part of government's environmental protection efforts. The Action Plan also builds upon the National EPA Pollution Prevention Strategy (56 FR 7849 (February 26, 1991)). The focus of the National strategy is to reduce the on-going generation of toxic pollution in any form (air emissions, waste water discharges, hazardous waste, runoff, or fugitive releases) through reduction in the use of toxic substances, process changes and product changes.

EPA and the Great Lakes States agreed to implement this effort to reduce the levels of toxic substances found in the Great Lakes basin by promoting pollution prevention activities to significantly reduce or eliminate the use and/or release of toxic substances at the source, with a special focus on reducing or eliminating persistent bioaccumulative toxic substances. EPA is currently promoting pollution prevention through a number of regulatory and non-regulatory activities. For example, EPA is implementing the National 33/50 Program in the Great Lakes System. Under this National program, EPA has received voluntary commitments from industry to reduce the emission of 17 priority pollutants by 33 percent by the end of 1992 and by 50 percent by the end of 1995. EPA has also been working with utilities located

within the Great Lakes basin to accelerate the phase-out of transformers containing PCBs. In addition, EPA and the Great Lakes States have undertaken many pollution prevention activities including "clean sweeps" which not only provide for the collection and environmentally safe disposal of contaminants, but also provide educational fact sheets to participants on how to prevent future pollution. These pollution prevention activities will complement other ongoing efforts to reduce toxics in the Great Lakes System.

3. Lakewide Management Plans (LaMPs)

In Article VI, Annex 2 of the Great Lakes Water Quality Agreement (GLWQA), as amended in 1987, the United States and Canadian Governments agreed to develop and implement Lakewide Management Plans (LaMPs) for each of the five Great Lakes. LaMPs are management tools designed to: (1) Integrate Federal, State and local programs to reduce loadings of toxic substances (including discharges from point and nonpoint sources); (2) assess whether these programs will ensure attainment of water quality standards and designated beneficial uses; and (3) recommend any media-specific program enhancements necessary to reduce toxic loadings in waters currently not attaining water quality standards and/or designated beneficial uses. LaMPs provide an opportunity for regulatory authorities to design cost-effective approaches for meeting water quality standards and/or beneficial uses.

The primary goal of the LaMPs is to reduce loadings of critical pollutants, those pollutants which are currently impairing the beneficial uses of the open waters of the Great Lakes. LaMPs are also pollution prevention-oriented and address pollutants that might impair waters that currently meet water quality standards and/or beneficial uses. Traditional regulatory programs, as well as non-traditional voluntary programs, are considered in the LaMP process.

LaMPs for each of the Great Lakes will be developed by EPA in phases. LaMP development activities were initiated for Lakes Michigan and Ontario in Federal fiscal year 1991, and for Lake Superior in fiscal year 1992. LaMPs for Lakes Erie and Huron will be initiated in fiscal years 1993 and 1994, respectively.

The Great Lakes Critical Programs Act of 1990 (CPA) established deadlines regarding the completion of the Lake Michigan LaMP. A notice of availability of the draft Lake Michigan LaMP was published in the **Federal Register** on August 11, 1992 (57 FR 358). Following the public review and comment period, the Lake Michigan LaMP will be revised and submitted to the International Joint Commission. The final Lake Michigan LaMP will be published in the **Federal Register**. The draft Lake Michigan LaMP has identified both immediate and long-term implementation actions to reduce loadings of critical pollutants. Three basic implementation steps are outlined: identification of all possible sources of pollutants; quantification of loadings from each source; and identification of load reduction activities with the greatest potential for pollutant reduction.

Development of the Lake Ontario Toxics Management Plan (LOTMP), the precursor to the Lake Ontario LaMP, was undertaken by EPA, Environment Canada, the New York State Department of Environmental Conservation and the Ontario Ministry of the Environment (the Four Parties) on February 4, 1987. The goal of the LOTMP is to ensure a Lake that provides drinking water and fish that are safe for unlimited human consumption, and allows natural reproduction within the ecosystem of the most sensitive native species including bald eagles, ospreys, mink and otters. The LOTMP addresses the bioaccumulation of toxic chemicals in fish flesh, the primary environmental problem identified in Lake Ontario. Initial toxic reduction efforts are focussed on 20 hazardous waste sites that contribute 99 percent of the total loadings of contaminants from waste sites to the Niagara River which flows into Lake Ontario.

The LaMP development effort for Lake Superior began as a component of the Bi-National Program to Restore and Protect the Lake Superior Basin. Lake Superior has not experienced the intense development, urbanization and pollution characteristic of the lower lakes and has remained relatively pristine. The focus of the Lake Superior LaMP, therefore, is on using Lake Superior as a demonstration area for new and innovative approaches to pollution prevention and zero discharge.

EPA intends to periodically update LaMPs to reflect progress in implementing media-specific programs and attendant reductions in toxic loadings, to incorporate advances in the understanding of the Great Lakes System based on new data and information, and to include any necessary program specific adjustments. In addition, EPA expects any new loadings data obtained during the LaMP process will be incorporated by the States when establishing or revising TMDLs and WLAs in the Great Lakes System. These new TMDLs and WLAs will then be appropriately reflected in subsequent revisions to NPDES permits.

4. Remedial Action Plans (RAPs)

The development and implementation of Remedial Action Plans (RAPs) is addressed in Annex 2 of the Great Lakes Water Quality Agreement. This section provides that United States and Canadian Governments will cooperate with State and Provincial Governments to ensure that RAPs are developed and implemented for specific Areas of Concern (AOCs) in the Great Lakes.

Forty-three AOCs have been designated by the United States and/or Canadian Governments: 26 located entirely within the United States; 12 located wholly within Canada; and five that are shared by both countries. RAPs are being developed for each of these AOCs that are designed to address impairments to any one of 14 beneficial uses (e.g., restrictions on fish and wildlife consumption, dredging activities, or drinking water consumption) associated with these areas.

RAPs are developed in three stages: The assessment of use impairments, the stresses and sources of the stresses in Areas of Concern (Stage I); proposed remedial actions and their method of implementation (Stage II); and evidence that uses have been restored (Stage III), including significant milestones in the restoration of beneficial uses in the AOCs. The eight Great Lakes States and the Province of Ontario have the lead in preparing and implementing the RAPs, but rely on the input and expertise provided by Federal agencies and organizations as well as local citizens groups and individuals. The Great Lakes Critical Programs Act of 1990 established deadlines for completion of RAPs for all AOCs in the United States. As a result, the pace of RAP development has been accelerated.

Remedial actions to restore impaired uses in AOCs are proceeding in all of the designated AOCs even if RAP documents have not been fully completed. For example, State and Federal enforcement actions have been taken against industrial dischargers for permit violations. Multi-year programs to eliminate or treat combined sewer overflows and upgrades to municipal sewage treatment plants have been undertaken by cities and municipalities. Superfund cleanups are in progress and EPA and the States have taken multiple remedial actions through hazardous waste programs. Additionally, Federal and State agricultural pollution control programs are also addressing problems in several AOCs.

5. Contaminated Sediments

The United States and Canadian Governments, in cooperation with State and Provincial governments, have agreed to identify the nature and extent of sediment pollution in the Great Lakes System pursuant to Annex 14 of the Great Lakes Water Quality Agreement. Based on these findings, the United States and Canada have agreed to develop methods to evaluate both the impact of polluted sediments on the System and the technological capabilities of programs to remedy such pollution. Information obtained through research and studies pursuant to Annex 14 will also be used to guide the development and implementation of RAPs and LaMPs. EPA is developing both National and Great Lakes-specific strategies to deal with this source of contamination in a comprehensive and systematic way.

Contaminated sediments are a significant source of loadings of toxic pollutants at harbors and river mouths throughout the Great Lakes System and identified as environmental problems in 42 of the 43 AOCs. Based on a preliminary review of Superfund case studies (including the Fieldbrook Superfund site in Ashtabula, Ohio), the benefits of remediating contaminated sediments are similar to, or exceed, the costs even when considering only the benefits of avoiding human cancer from consumption of contaminated fish. If economic values could also be assigned to the values of noncancer health effects and the negative ecological effects, the benefits would be even greater.

In order to design appropriate, cost-effective remediation measures, information at each site is needed on the distribution and surface area of contaminated sediments, their depth and volume, chemicals present, toxicity of the chemicals, potential for sediment transport and redistribution, and the movement of the chemicals from the sediments to the water and to aquatic communities.

The 1987 Clean Water Act authorized a five-year demonstration program to develop technologies to treat contaminated sediments in the Great Lakes. This program, known as the Assessment and Remediation of Contaminated Sediments (ARCS) Program, is designed to evaluate appropriate treatment methodologies for the cleanup of toxic pollutants in Great Lakes contaminated sediments. The IJC has identified contaminated sediments as a problem in 42 out of 43 United States and Canadian AOCs. Additionally, EPA and local RAP teams have cited contaminated sediments as a problem in all 31 United States and joint United States/Canadian AOCs. Under this program, United States demonstrations of alternative treatment technologies are underway.

The ARCS Program has used an integrated approach involving over 40 agencies and organizations in developing and testing assessment and remedial action alternatives for contaminated sediments. The overall objectives of the ARCS Program are to: Develop and demonstrate tools and approaches for assessing the nature and extent of bottom sediment contamination at selected Great Lakes AOCs; develop tools to predict the consequences of remedial actions being proposed; and demonstrate and evaluate the effectiveness of selected remedial options, including removal, immobilization and advanced treatment technologies.

This Program demonstrates state-of-the-art methods for the assessment of contaminated sediments. A mass balance approach is being applied to assess all impacts within an AOC and to predict the benefits from a range of cleanup scenarios. Both bench and on-site pilot demonstrations are being conducted at five priority AOCs in order to evaluate different assessment and remediation options and to provide environmental decision-makers with guidance on how to eliminate problems posed by contaminated sediments. Final guidance documents on field assessments, risk assessments and modeling, and remedial technologies will provide guidance for future, full-scale cleanup efforts.

EPA is preparing to publish for public comment proposed sediment quality criteria for acenaphthene, dieldrin, endrin, fluoranthene, and phenanthrene. EPA is also developing a National Contaminated Sediment Strategy, which is expected to include comprehensive strategies on sediment assessment, prevention, remediation, and dredged material management. EPA's draft nationwide contaminated sediment management strategy proposes the use of four statutes (the Comprehensive Environmental Response, Compensation, and Liability Act, the Resource Conservation and Recovery Act, the Toxic Substances Control Act, and the Clean Water Act) to achieve active remediation of contaminated sediments. The Great Lakes ARCS Program is an essential component of the National Strategy. Implementation of the strategy will provide reductions in loadings of pollutants impairing water quality of the Great Lakes System and preventing attainment of beneficial uses.

In the assessment strategy, EPA is proposing to develop a national inventory of contaminated sediment sites and a pilot inventory of potential sources of sediment contamination, based on data from the ARCS Program as well as on other databases. The inventories will enable EPA's prevention and remediation programs to focus resources on addressing top priority sites and sources. The assessment strategy proposes to develop a consistent, tiered testing protocol that will include a minimum set of chemical and biological methods that all EPA programs will use to determine if sediments are contaminated. EPA is also developing sediment chemical criteria to be used in sediment assessment. The prevention strategy discusses a variety of pollution prevention measures and source controls, including nationally applicable responses, such as prohibitions or use restrictions under TSCA or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), technology-based effluent limitations for industrial dischargers under the Clean Water Act, and a National initiative to revise water quality-based effluent limits in NPDES permits. The remediation strategy emphasizes appropriate control of sources prior to remediation efforts unless the contaminated sediments pose a sufficiently great hazard to human or environmental health to warrant immediate remediation. Factors that will be considered in implementing this strategy include:

(1) Whether the sediment contamination is contributing to severe effects or substantial risks to aquatic life, wildlife or human health;

(2) Whether continued delay in removing the sediment would result in the spread of harmful contamination over a wider area or into important habitats;

(3) The likelihood of contaminated sediments that are left in place at a specific site to be transported to downstream or offshore areas;

(4) The timeframe for natural recovery; the potential for contaminant mobilization during remediation; and

(5) The feasibility and cost of various treatment and removal options.

Cleanups of contaminated sediments are occurring through the RAP process and as a result of EPA's enforcement program. Examples include fifty thousand cubic yards of contaminated sediment removed from the Black River, Ohio, cleanup of one million pounds of PCBs, initiated through a Superfund enforcement action in Waukegan Harbor, Illinois, and sediment cleanup and environmental improvements

provided for in a $34 million settlement in the Grand Calumet River, Indiana.

6. Atmospheric Deposition

Airborne deposition of pollutants is believed to have a significant impact on the water quality of the Great Lakes System. The Great Lakes Water Quality Agreement provides that the United States and Canada, in cooperation with the Great Lakes States and the Province of Ontario, shall conduct research, surveillance, and monitoring, and implement pollution control measures for the purpose of reducing atmospheric deposition of toxic substances, particularly persistent toxic substances, to the Great Lakes Basin Ecosystem (Annexes 11 and 15). To implement these provisions, the United States and Canada established an Integrated Atmospheric Deposition Network as part of the Great Lakes International Surveillance Plan to monitor atmospheric loadings of toxic substances to the Great Lakes System.

Implementation of the major provisions of the Clean Air Act Amendments of 1990 (CAAA) is an integral part of EPA's broader program to protect and restore the Great Lakes. By November 15, 1993, then every two years thereafter, EPA (in cooperation with the Department of Commerce) is required by section 112(m) of the CAAA to report to Congress concerning the results of the Great Lakes monitoring studies and describe any revisions to Federal law necessary to ensure protection of human health and the environment in the Great Lakes System. The report will determine whether provisions of section 112 are adequate to prevent serious adverse effects to public health and serious or widespread environmental effects. Based on the report, EPA is required by November 15, 1995, to promulgate further emission standards or control measures if necessary to prevent such effects.

Section 112(m) also requires the establishment of at least one master wet/dry facility on each of the five Great Lakes to monitor toxic deposition in wet and dry conditions as part of the Great Lakes Air Deposition (GLAD) and International Air Deposition (IADN) networks. The GLAD network includes 22 satellite stations that monitor metals and conventional pollutants. The United States and Canadian Implementation Plan for the IADN master stations was revised and accelerated in order to meet the deadlines imposed by the CAAA. Data supplied by this effort will be used to identify and track movement of hazardous air pollutants; determine loadings due to atmospheric deposition; and support development of RAPs and LaMPs. Other regulatory programs are subject to the requirements of antidegradation if they have independent regulatory authority requiring compliance with water quality standards. Section 112(m) of the Clean Air Act has such requirements.

In accordance with section 182 of the CAAA of 1990, States with areas designated non-attainment for ozone must submit revisions to their implementation plans providing for a 15 percent reduction in volatile organic compound (VOC) emissions, to be achieved by November 15, 1996. As many VOCs are also toxic air pollutants, the 15 percent VOC reduction will include reductions in numerous air toxics. Implementation of regulatory programs that reduce the emissions of VOCs and particulate matter will benefit the water quality of the Great Lakes System by decreasing atmospheric deposition to the System.

In addition, between 1992 and 2000, EPA must promulgate technology-based emission standards for all source categories of the 189 toxic air pollutants listed in section 112(b) of the CAAA. In setting these standards, EPA will consider inter-media transfer effects. Such standards must be fully implemented by November 15, 2003, and will apply to all major stationary sources and some area sources of the listed pollutants in the States adjacent to the Great Lakes System. Under section 112(f), these Standards will be followed between 2001 and 2008 by risk-based standards, where necessary, to ensure that public health is protected with an ample margin of safety and to ensure adverse environmental effects are prevented subject to cost, energy and safety considerations. Under section 112, EPA may add additional substances to the list of toxic air pollutants (including pollutants of concern in the Great Lakes) when scientific information dictates additions are warranted.

Title IV of the CAAA provides for a reduction in SO_2 from utilities of approximately 10 million tons by 2010. Not only will a portion of this reduction occur in the Great Lakes, but many of the control technologies permittees are likely to use to achieve these reductions may reduce toxic air pollutants, such as mercury, that are specifically of concern in the Great Lakes System.

Finally, under Title II of the CAAA, substantial nationwide reductions in VOC emissions from motor vehicles will be achieved, including reductions in toxic pollutants. Title II also requires EPA to conduct a study of mobile source toxic emissions and promulgate regulations to control air toxic emissions from motor vehicles by May 15, 1995. Such regulations, by reducing air toxics emissions nationwide will benefit the water quality of the Great Lakes System by reducing loadings from atmospheric deposition.

7. Storm Water

The 1987 amendments to the Clean Water Act, section 402(p), required EPA to establish a comprehensive, two-phased approach for controlling storm water discharges. In Phase I, the CWA required EPA to develop NPDES permit application requirements for two major classes of dischargers: large (over 250,000 population served) and medium (100,000–250,000 population served) sized municipal separate storm sewer systems; and storm water discharges "associated with industrial activity." Congress also included two other classes of storm water discharges in Phase I: discharges which had already obtained a permit prior to February 4, 1987, and discharges which EPA or a NPDES State determines contribute to a violation of a water quality standard or is a significant contributor of pollutants to the waters of the United States. The 1987 Amendments, as further amended by section 312 of the Water Resources Development Act of 1992, prohibit EPA and NPDES States from requiring permits for the remaining classes and sources of storm water discharges (Phase II) prior to October 1, 1994.

The storm water permit application Phase I regulations, promulgated on November 16, 1990, established the scope of the program. The rule identified 220 large and medium municipal separate storm sewer systems (173 cities and 47 counties) for permitting, defined what constitutes a storm water discharge "associated with industrial activity," and established specific permit application requirements and deadlines. Permit application requirements for large and medium municipal separate storm sewer systems require them to propose storm water management programs to control storm water discharges to the "maximum extent practicable," and to effectively prohibit non-storm water discharges to the storm sewer system. The 1990 definition of storm water discharges "associated with industrial activity" includes industrial facilities in the Great Lakes System in such industries as mining, manufacturing, hazardous waste treatment, storage and disposal facilities, landfills, power plants and transportation facilities. These facilities must comply with individual or group NPDES permit application requirements, or meet

requirements specified in general permits. The controls imposed on the storm water discharges from these facilities in individual or general permits will significantly reduce the loadings of pollutants to the Great Lakes System.

8. Combined Sewer Overflows (CSOs)

EPA is currently improving and accelerating implementation of the National Combined Sewer Overflow Control Strategy (54 FR 37370, Sept. 8, 1989). As part of this effort, EPA issued on January 19, 1993, a draft policy that more clearly defines EPA's interpretation of the appropriate technology-based and water quality-based requirements to be included in NPDES permits to control these point source discharges nationwide. See 58 FR 4994. Representatives of publicly owned treatment works, States and environmental groups participated in developing the permitting component of the draft policy, which also contains an enforcement component. EPA expects to issue the policy in final form during 1993. Additional ongoing efforts to address CSOs in the Great Lakes System and the application of the proposed Guidance to those discharges are discussed in section II.E.2.b.1 of this preamble.

9. Discharges of Oil and Hazardous Polluting Substances

Annexes 4, 5, 6, 8, and 9 of the Great Lakes Water Quality Agreement address the discharges of oil and hazardous polluting substances into the Great Lakes, including discharges of oil and hazardous polluting substances from vessels, discharges of vessel wastes, pollution from shipping sources, discharges from onshore and offshore facilities, and joint contingency plans. EPA has initiated several programs recently to address oil spill prevention and control measures nationally and in the Great Lakes System. For example, EPA proposed a revised Spill Prevention Control and Countermeasures (SPCC) regulation (40 CFR part 112) in the **Federal Register** on October 22, 1991 (56 FR 54612). The proposed rule is intended to clarify existing regulatory language. EPA also published a proposed rule in the **Federal Register** on February 17, 1993, (58 FR 8824) addressing facility response plans required under CWA section 311(j)(5), added by the Oil Pollution Act of 1990. Further, EPA targeted 182 SPCC inspections in the Great Lakes System during fiscal year 1991 and completed 196.

Additionally, the Oil Pollution Act of 1990 strengthens United States programs for preventing and responding to spills. Research conducted under Title VII of the OPA to assess the Oil Pollution Act of 1990 strengthens United States programs for preventing and responding to spills. Research conducted under Title VII of the OPA to assess the status of navigation safety, state-of-the-art pollution prevention techniques, and development of efficient oil spill response techniques will benefit the Great Lakes System. EPA and the Coast Guard have mapped areas of the Great Lakes which may be vulnerable to spills and are identifying potential weaknesses in current prevention and response programs.

10. Nonpoint Sources of Pollution From Land-Use Activities

Annex 13 of the Great Lakes Water Quality Agreement addresses programs and measures for the abatement and reduction of nonpoint sources of pollution from land-use activities. The annex addresses efforts to further reduce nonpoint source contributions of phosphorus, sediments, toxic substances and microbiological contaminants contained in drainage from urban and rural land, including waste disposal sites, in the Great Lakes System.

Section 118(c)(6) of the Clean Water Act requires EPA in consultation with the Great Lakes States to develop a five-year plan and program to reduce nutrient loadings to the Great Lakes. EPA has implemented this requirement within the existing water quality management framework, including through development of Phosphorus Load Reduction Plans. Interagency task forces in each of the Great Lakes States have developed individual State Phosphorus Load Reduction Plans to achieve full compliance with point source discharge limits and reduction of agricultural phosphorus loads through conservation tillage and better nutrient management. Based on these plans, the Phosphorus Load Reduction Task Force has prepared load reduction plans outlining State and Federal efforts necessary to ensure that each State meets its target load reduction.

In addition, the Coastal Zone Act Reauthorization Amendments of 1990 (CZARA) make available to eligible States funds for the development of nonpoint control programs to restore and protect coastal waters, such as the Great Lakes. Under the CZARA, Michigan, New York, Pennsylvania and Wisconsin, as coastal States with federally approved coastal management programs, are required to develop programs containing enforceable policies and mechanisms in order to ensure implementation of management measures to address nonpoint pollution from agricultural, urban and silvicultural runoff and other sources. Participating States must submit their programs to EPA and the National Oceanic and Atmospheric Administration for approval within two and a half years of EPA's publication of final guidance specifying nonpoint source management measures. Final guidance was published on January 19, 1993. See 58 FR 5182. States failing to submit approvable programs will lose grant funds that would otherwise be awarded under section 319 of the Clean Water Act and section 306 of the Coastal Zone Management Act.

There is general agreement that nonpoint sources of pollution (e.g., any diffuse source of pollutant loadings to the waters of the Great Lakes System, such as contaminated sediments, air deposition, spills, etc., as well as agricultural and urban runoff) are a significant remaining cause of environmental risk in the Great Lakes Basin Ecosystem. In the December 16, 1992, report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," the SAB endorsed the broad based ecosystem approach of the Initiative, but stated that it was not clear what specific mechanisms the Great Lakes Guidance had incorporated to address pollution from these nonpoint sources.

In addition to the ongoing State and Federal programs described above, the proposed Guidance affects nonpoint sources in two ways. First, the water quality criteria and values in the proposed Guidance apply to the ambient waters of the Great Lakes System, regardless of the source of pollutants to those waters. Although criteria by themselves are not directly enforceable under Federal law, procedure 3 of appendix F (Total Maximum Daily Loads) addresses nonpoint sources by requiring allocation of the available load capacity of the receiving water among all sources of the pollutant, including nonpoint sources. Second, any regulatory programs controlling nonpoint sources developed by States or Tribes would also be subject to the antidegradation procedures in the proposed Guidance.

Further, by establishing numeric water quality criteria and values for the protection of aquatic life, wildlife and human health which apply to the ambient waters of the Great Lakes System, regardless of the source of pollutants to those waters, the proposed Guidance provides the basis for integrating actions carried out under the range of environmental programs

available to both Federal, State and Tribal regulators in order to protect and restore the Great Lakes Basin Ecosystem. In this manner, EPA believes the proposed Guidance is consistent with and furthers an ecosystem approach.

Additionally, as described in section II.G.12 below, EPA and the Great Lakes States have established a new program, the Great Lakes Toxic Reduction Initiative, to evaluate the development of specific programs and implementation procedures to control loadings of pollutants to the waters of the Great Lakes System from nonpoint sources. Development of such programs would further reduce pollutant loadings to the waters of the Great Lakes System and facilitate equitable division of the costs of any necessary control measures necessary to attain water quality standards among point and nonpoint sources.

11. Great Lakes Fish Advisories

The Great Lakes States currently have issued 164 fish consumption advisories that are currently in effect for various waters of the Great Lakes System. In the United States, the States have the primary responsibility for advising the public of the risks associated with the consumption of sport-caught fish. If a potential local health threat exists, a State may choose to issue warnings or provide guidance on the quantity of contaminated fish which may be consumed. In recent years, while the number of restrictions on eating Great Lakes fish has declined, State officials recommend the continued adherence to guidelines for sport fish consumption. The Great Lakes States are presently reviewing and strengthening the procedures for issuance of fish advisories in the Great Lakes System, particularly as they pertain to certain more-affected segments of the population, such as subsistence and sports fishers. This effort also includes an evaluation of the issuance of joint fish consumption advisories on multi-jurisdictional lakes. A Fish Advisory Task Force, composed of representatives from each Great Lake State and EPA, is currently developing a common fish advisory protocol. This protocol will consider the possible reproductive impacts and other relevant toxicological endpoints associated with the consumption of contaminated Great Lakes fish. Such an approach, once adopted and implemented, will provide enhanced, consistent, risk-based protection of human health.

12. Environmental Monitoring and Data Management Programs for the Great Lakes

EPA has established the Environmental Monitoring and Assessment Program (EMAP) to provide a comprehensive program to monitor the condition of the nation's ecological resources. The Great Lakes are one of seven basic resource groups included within EMAP (EMAP–GL) which also covers the coordination of environmental indicators, statistical design and analyses, landscape characterization, integration and assessment, quality assurance, information management, geographical information services and logistics. The data collected under EMAP–GL is intended to describe current conditions within the Great Lakes System, report on ecological trends using a set of environmental indicators on a lakewide scale or resolution and evaluate long-term changes in the condition of the Great Lakes System as a result of management and regulatory programs.

The Great Lakes National Program Office is developing a comprehensive data integration and management strategy for EPA's Great Lakes programs. When implemented, the strategy will support Federal, State and local efforts to restore and maintain the chemical, physical and biological integrity of the waters of the Great Lakes Basin Ecosystem. EPA expects the strategy to be completed in 1993.

13. Great Lakes Toxic Reductions Initiative Multi-media Management Committee

EPA believes an ecosystem approach to addressing the environmental problems of the Great Lakes defines the need to establish consistent, uniform programs to reduce loadings of toxic pollutants to the waters of the Great Lakes System from all sources. This ecosystem approach is reflected in the Great Lakes Five Year Strategy (discussed in section I.G.1), which commits the States, Tribes and Federal Agencies responsible for environmental protection and resource management in the Great Lakes Basin to achieving specific environmental goals. Specifically, in the area of toxics reductions, the Strategy calls for [reducing] the level of toxic substances in the Great Lakes System with an emphasis on persistent toxic substances, so that all organisms are adequately protected and toxic substances are virtually eliminated from the Great Lakes ecosystem. As discussed above, a wide range of pollution control, abatement and prevention activities are currently underway throughout the Great Lakes Basin, implementing numerous statutes and policies at the Federal, State and local levels.

Further, EPA believes that the water quality criteria, methodologies, implementation procedures and antidegradation provisions in the proposed Guidance satisfy the requirements of section 118(c)(2) of the CWA and will greatly advance the CWA and GLWQA goals to restore and maintain the integrity of the Great Lakes System. EPA recognizes, however, that full achievement of these goals depends upon the successful implementation of a variety of media-specific programs.

Accordingly, EPA and the Great Lakes States agreed to establish a multi-media process through the "Great Lakes Toxics Reduction Initiative" (GLTxRI) to identify and address any gaps or barriers to establishing uniform consistent load reduction programs for sources which effect the Great Lakes Basin Ecosystem, including whether additional guidance or policies should be developed for any particular discharges of toxic pollutants of concern to the waters of the Great Lakes System. A primary goal of the GLTxRI is to establish a consistent, uniform approach across all media to reduce loadings of toxic pollutants to the waters of the Great Lakes System, and accelerating scheduled actions in order to achieve necessary reductions.

The range of sources of toxic pollutants to be addressed under the GLTxRI includes, but is not limited to—agricultural nonpoint sources, wet-weather point source discharges, hazardous waste sites, air deposition, contaminated sediments and spills due to storage, handling or transport activities. In conjunction with the numeric water quality criteria and values, implementing procedures and antidegradation policies established through the final publication of the Great Lakes Water Quality Guidance, this process will provide EPA and the Great Lakes States and Tribes with a comprehensive, integrated framework for reducing toxic loadings to the waters of the Great Lakes System, with the goal of virtually eliminating toxic pollutants. Of specific concern to EPA and the States is the reduction of those pollutants classified as Bioaccumulative Chemicals of Concern in the proposed Guidance, as they pose the greatest risk to the Great Lakes Basin Ecosystem in terms of systemwide impacts. Together, these activities will enable EPA and the Great Lakes States and Tribes to develop cost-effective strategies to further the goals and requirements of the CWA and the GLWQA, and ensure attainment of the water quality criteria and values

established through the publication of the final Great Lakes Guidance.

One particular issue the GLTxRI management committee will focus on is the inter-media transfer of pollutants. EPA and the Great Lakes States are concerned that future reductions in loadings of toxic pollutants to the water may cause the transfer of pollutants from one media to another—e.g., from water to air—rather than overall reductions in loadings to the environment. As a result of this concern, the GLTxRI management committee will identify and evaluate measures for minimizing inter-media transfers. Possible measures for consideration include whether a permittee shall be required to provide information on how it will comply with any more stringent limitations in a draft permit, including information relevant to the transfer of pollutants from one medium to another, whether the reduction would be attributable to source reduction techniques, and whether the facility has evaluated any alternative pollution prevention measures.

The SAB in its December 18, 1992, report, Evaluation of the Guidance for the Great Lakes Water Quality Initiative, recommended that EPA promote a broadly based ecosystem approach which considers not only point source discharges but nonpoint sources, sediments, atmospheric fall-out, and groundwater as targets for conservation and control of undesirable loadings. EPA believes through implementing the full range of existing regulatory and voluntary programs described above to prevent pollutants from being introduced, reduce pollutant loadings currently being discharged, and remediate the adverse effects associated with past pollutant discharge to the Great Lakes System, a comprehensive ecosystem approach to protecting and restoring the Great Lakes is being actively pursued by EPA and the Great Lakes States and Tribes. Further, EPA believes the application of the numeric water quality criteria and values proposed in the proposed Guidance to the ambient waters of the Great Lakes System, regardless of the source of pollutants to those waters, is consistent with and promotes the ecosystem approach.

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II. Regulatory Requirements

The proposed Guidance consists of a new part 132 of Title 40, Water Quality Guidance for the Great Lakes System. This section of the preamble describes the overall regulatory requirements that EPA proposes for adoption by the Great Lakes States and Great Lakes Tribes.

A. Scope and Purpose

The Guidance consists of regulatory requirements, contained in part 132, including six appendixes that provide the text of the Water Quality Guidance that the Great Lakes States and Tribes must adopt into their laws and regulations. Part 132 as a whole constitutes the Water Quality Guidance for the Great Lakes System required by section 118(c)(2) of the Clean Water Act (Pub. L. 92–500 as amended by the Great Lakes Critical Programs Act of 1990, Pub. L. 101–596).

Today's proposal also is intended to satisfy the requirements of section 118(c)(7)(C) of the Clean Water Act that EPA publish information concerning the public health and environmental consequences of contaminants in Great Lakes sediment and that the information include specific numerical limits to protect health, aquatic life, and wildlife from the bioaccumulation of toxins.

The Guidance has three major purposes. First, it provides guidance to the Great Lakes States and Tribes on minimum water quality standards. To accomplish this, the Guidance contains numerical water quality criteria for 32 pollutants, listed in Tables 1, 2, 3 and 4 in § 132.3. The Guidance also contains methodologies for the development of water quality criteria and water quality values for the protection of aquatic life, human health, and wildlife, and a methodology for development of bioaccumulation factors, in appendixes A, B, C and D. Together, these criteria and methodologies specify numerical limits on pollutants in ambient Great Lakes waters to protect human health, aquatic life, and wildlife.

The second purpose of the proposed Guidance is to provide guidance to the Great Lakes States and Tribes on antidegradation policies and to require adoption of the Antidegradation Standard, the Antidegradation Implementation Procedures, the Antidegradation Demonstration provisions, and the Antidegradation Decision provisions in appendix E.

The third purpose of the proposed Guidance is to provide guidance on implementation procedures, through the Water Quality Guidance Implementation Procedures at § 132.5 and in appendix F. Some portions of the Implementation Procedures also affect the adoption of minimum water quality standards.

B. Definitions

Section 132.2 of the proposed Guidance contains definitions which apply to this part. Section 132.2 is a partial list of terms which need to be defined for consistent interpretation of the Guidance in this part. Section 132.4(a) of the proposal requires Great Lakes States and Tribes to adopt these definitions as part of their water quality standards or approved NPDES programs. Other definitions, bearing on the individual portions of the Guidance, are contained in appendixes A through F. Generally, where terms have been applied in the Guidance in the same manner as in previous National regulations, such as those in 40 CFR 122.2, 130.2, and 131.3, a duplicate definition has not been provided. However, in some cases, duplicate definitions have been provided to assist the reader. The following paragraphs describe the origin of the terms defined in § 132.2.

The definition of "Great Lakes System" is from section 118 of the Clean Water Act (CWA) and the Great Lakes Water Quality Agreement (GLWQA or Agreement). It is provided for the convenience of the reader. Great Lakes States and Tribes must apply the provisions of the Guidance to all portions of the Great Lakes System within their jurisdiction. Waters of the Great Lakes System located within the United States are "waters of the United States" as defined in 40 CFR 122.2.

The terms "connecting channels of the Great Lakes" and "Great Lakes" are from section 118 of the Clean Water Act.

The terms "load allocation," "loading capacity," "total maximum daily load" and "wasteload allocation" are duplicated from 40 CFR part 130, and are included in this proposed Guidance to assist the reader. EPA requests comments on the use of these definitions in part 132. However, EPA is not proposing today to revise 40 CFR part 130, and is therefore not soliciting comments on 40 CFR part 130.

The terms "existing uses," "Federal Indian reservation" and "Indian Tribe" are duplicated from 40 CFR 131.3, and are included in this proposed Guidance to assist the reader.

The terms "acute/chronic ratio," "acute toxic unit (TU_a)," "chronic toxic unit (TU_c)," "EC50," and "no observed effect concentration" are adapted from the March 1991 EPA guidance document, "Technical Support Document for Water Quality-based Toxics Control (TSD)." The TSD has undergone extensive peer review, and EPA believes the technical definitions derived from the TSD are valid technically and scientifically. However, there may be policy or administrative implications from adopting these definitions in the proposed Guidance that were not considered at the time the TSD was developed. EPA invites comment on the use of these definitions in part 132. However, EPA is not proposing today to revise the TSD, and is therefore not soliciting comments on the TSD in this proposed rulemaking.

The terms "open waters of the Great Lakes" and "tributaries of the Great Lakes System" were developed primarily to facilitate application of requirements that, for technical reasons,

have different application or effects depending on the type of water body. EPA invites comments on these definitions.

The term "bioaccumulative chemical of concern" is discussed in section II.G of this preamble.

The term "wet weather point source" is discussed in section II.E of this preamble.

The term "Great Lakes States and Great Lakes Tribes" is defined in the proposed Guidance to clarify which States contain portions of the Great Lakes System within their boundaries (i.e., Illinois, Indiana, Ohio, Michigan, Minnesota, New York, Pennsylvania, and Wisconsin). The proposal also includes within the definition any Indian Tribe as defined below whose reservation lies in whole or in part within the drainage basin of the Great Lakes, and that EPA has determined qualifies under section 518 of the Clean Water Act to administer programs under sections 303 (see 40 CFR 131.8) and/or 402 of the Clean Water Act.

The proposal includes Indian Tribes in this definition because section 118(c) requires the water quality guidance to apply to the Great Lakes System, and some portions of the Great Lakes System are located within the boundaries of Indian Reservations. Tribes are not required to apply for authorization to administer programs under sections 303 or 402 of the Clean Water Act. However, if they do, they are required to adopt requirements consistent with section 118 of the Clean Water Act and the final Guidance adopted in part 132 in order to control discharges into the Great Lakes System to the same extent as Great Lakes States. If they do not, EPA or State water quality standards which may apply to Indian Reservations must incorporate the requirements of part 132, and EPA will incorporate the requirements of this part into EPA-issued permits for discharges on Indian Reservations. For further discussion of how the water quality standards program operates on Indian Reservations, see 54 FR 64891 (Dec. 12, 1991).

EPA believes that inclusion of Indian Tribes in the proposed Guidance is consistent with section 518 of the Clean Water Act. While section 518(e) does not explicitly address Tribal assumption of responsibilities under section 118(c)(2), it does address water quality standards and NPDES programs which are the base programs addressed by the section 118(c)(2) requirements. Section 518 clearly allows Indian Tribes to be authorized to administer both water quality standards and NPDES programs, and EPA sees no reason why Indian Tribes should not be similarly treated for purposes of section 118(c)(2). Indeed, were EPA not to require that Indian Tribes comply with the proposed requirements in the proposed Guidance, there could be a gap in the protection of the Great Lakes System. EPA does not believe that Congress would have intended this result.

EPA invites comment on the inclusion of Indian Tribes in this definition, including the policy, administrative and resource implications of requiring Indian Tribes who are authorized to administer programs under sections 303 and/or 402 to adopt the provisions of this Guidance. At this time, there are no Indian Tribes authorized to administer programs under either section 303 or section 402 within the boundaries of the Great Lakes System. EPA intends to work with the Great Lakes Indian Tribes on a government-to-government basis to provide them with a greater understanding of the Great Lakes Guidance and its impact on Tribal governments. To achieve this, EPA plans to develop a specific outreach program with the Great Lakes Tribes within the context of a broader public forum to inform the public on the elements of the Guidance.

The terms "carcinogen," "noncarcinogen," "quantitative structure activity relationship," "slope factor," "threshold effect," and "uncertainty factors" are derived from EPA's risk assessment methodologies, and were adapted for application in this Guidance. These terms and their usage are discussed in sections V and VI of this preamble.

The terms "compliance evaluation level," "detection level," "minimum level," and "quantification level" are discussed in section VIII.H of this preamble. The term "detection level" is from 40 CFR 136.2(f), and is provided for the convenience of the reader.

The terms "acceptable daily exposure," "acute toxicity," "adverse effect," "bioaccumulation factor," "bioaccumulation," "bioconcentration," "bioconcentration factor," "biomagnification," "chronic toxicity," "depuration," "LC50," "linear multi-stage model," "lowest observed adverse effect level," "no observed adverse effect level," "octanol-water partition coefficient," "relative source contribution," "steady state BAF/BCF," "superlipophilic chemical," and "uptake" are derived from common usage by toxicologists and biologists, and were adapted for application in this proposed Guidance. These terms are discussed further in sections III through VI of this preamble, in appendixes A through D, and in the corresponding Technical Support Documents.

The term "threatened or endangered species" is defined for the purposes of the proposed Guidance as those species that are listed as threatened or endangered under the Federal Endangered Species Act. This definition is discussed in section II.K of this preamble.

The terms "human cancer criterion," "human cancer value," "human noncancer criterion," "human noncancer value," and "risk associated dose" are discussed in section V of this preamble. The selection of the one in 100,000 risk level for human cancer criteria and values, and risk associated dose, is also discussed further in section V.

The terms "criterion continuous concentration," "criterion maximum concentration," "final acute value," "final chronic value," "final plant value," "genus mean acute value," "genus mean chronic value," "species mean acute value," and "species mean chronic value" were adapted from EPA's "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (Stephan, et al., 1985) for application in the proposed Guidance. These terms are explained more fully in appendix A of the proposed Guidance and in section III of this preamble.

The terms "Tier I criteria" and "Tier II values" are provided to differentiate between products of Tier I methodologies which either have been adopted as numeric criteria into water quality standards or are used to implement narrative criteria ("Tier I criteria"); and products of Tier II methodologies which are used to implement narrative water quality criteria ("Tier II values"). Sections III, V and VI of this preamble explain the use of Tier I and II methodologies in this proposed Guidance. EPA invites comment on these definitions.

The terms "allowable dilution flow (Q_{ad})," "dilution fraction," and "stream design flow" are discussed in section VIII.C of this preamble.

EPA invites comment on all definitions used in the proposed Guidance. EPA also invites comments on whether additional terms should be defined in this part.

C. Adoption of Criteria, Methodologies, and Procedures

Section 132.3 of the proposed Guidance requires Great Lakes States and Tribes to adopt numeric criteria for 16 pollutants for the protection of aquatic life, listed in Tables 1 and 2;

numeric criteria for 20 pollutants for the protection of human health, listed in Table 3; and numeric criteria for 4 pollutants for the protection of wildlife, listed in Table 4. Section 132.4 of the proposed Guidance requires Great Lakes States and Tribes to adopt the methodologies for developing numeric water quality criteria and values to protect aquatic life, human health, and wildlife specified in appendixes A through D. Section 132.4 also requires Great Lakes States and Tribes to adopt the Antidegradation Policy in appendix E and the Implementation Procedures in appendix F.

The Great Lakes Initiative Committees developed the basis for the procedures required in the proposed Guidance because of a strong concern about the environmental problems in the Great Lakes System and a concern that differences in water quality standards, antidegradation policies, and implementation procedures were leading to significant inconsistencies in regulatory approaches between the States. For example, human health criteria for mercury range from 0.0069 µg/L in one Great Lakes State, to 2.0 µg/L in another, with no two States having the same value. Similarly, aquatic life chronic criteria for cadmium range from 0.471 µg/L to 1.4 µg/L, and human health criteria for benzene range from 0.7 µg/L to 710.0 µg/L. As another example, only two States have developed explicit water quality criteria for the protection of wildlife. Further examples of significant differences between existing water quality programs include:

1. The use by some States of bioaccumulation factors when calculating exposure, while other States use the less restrictive bioconcentration factors. These practices can lead to differences of several orders of magnitude in the stringency of water quality-based controls.

2. The use of different "translator" methodologies in developing derived numeric criteria for implementing narrative water quality criteria.

3. The use of different assumptions when calculating total maximum daily loads and waste load allocations. For example, different assumptions about background concentrations, mixing zones, receiving water flows, or environmental fate can each individually result in orders of magnitude differences in water quality-based effluent limits in NPDES discharge permits.

4. The use of different practices in deciding what pollutants need to be regulated in a discharge, what effect detection limits have on compliance determinations, and how to develop whole effluent toxicity limitations.

For these reasons, the Steering Committee chose to develop guidance on those aspects of current State water quality standards programs and implementation procedures which have led to the most serious inconsistencies among the Great Lakes States' water quality programs. In order to maximize use of available time and resources, the Steering Committee did not develop guidance on areas that were currently being addressed through other programs or initiatives, or for implementation procedures that relied primarily on best professional judgment determinations of permitting authorities. The Steering Committee believed that uniform requirements were most necessary for the criteria methodologies, antidegradation policies, and selected implementation procedures to ensure consistent permit limitations for similar discharges throughout the Great Lakes basin. The results of the Steering Committee's work formed the basis for EPA's development of the proposed Guidance.

The areas not addressed in the proposed Guidance would continue to be subject to all applicable Federal, State, or Tribal requirements or guidance. For example, the EPA guidance document "Technical Support Document for Water Quality-based Toxics Control" (March 1991) remains fully applicable as evidence within the Great Lakes System for topics that have not been addressed by the proposed Guidance, and fully applicable as guidance for all topics for waters outside the Great Lakes System.

D. Application of Methodologies, Policies, and Procedures

1. The Two-Tiered Approach

The Initiative Committees were concerned that traditional criteria development methodologies would not be adequate to address the wide range of pollutants in the Great Lakes System. In particular, in order to assure the scientific validity of criteria as protective of designated uses, criteria methodologies include minimum requirements for toxicological data that may be difficult to meet except for a limited number of well-studied pollutants. In many cases, the full complement of toxicity data is not available for a particular pollutant which is nevertheless known or expected to cause adverse effects to humans, aquatic life, and wildlife. Some of the Great Lakes States currently have procedures that are intended for use as translator mechanisms to derive numeric ambient pollutant concentrations that will implement, in conjunction with the proposed whole effluent toxicity requirements, the States' narrative criteria (e.g., "no toxic substances in toxic amounts"). The Initiative Committees wanted to ensure consistency among States in the Great Lakes System as to how limited data are used to derive values for regulating discharges. The Initiative Committees also wanted to develop a methodology to be used as a translator mechanism common to all Great Lakes States that could be used in setting permit limits for the Great Lakes System.

To address these needs, the Committees developed a two-tiered approach, including:

a. Traditional criteria development methodologies, to enable development of water quality criteria (Tier I); and

b. Methodologies under which water quality values (Tier II) could be calculated with fewer data than the full minimum data required for a Tier I criterion calculation. The purpose of Tier II methodologies is to provide Great Lakes States with guidance on evaluating pollutants when there is insufficient data to develop Tier I criteria.

The Initiative Committees intended that the outcome of a Tier II analysis would be a somewhat conservative value to reflect the increased uncertainty surrounding a more limited database. For example, for aquatic life criteria, this consideration resulted in the development of a methodology which generally produces more stringent (lower) values where there are fewer data, and less stringent values as the database increases.

EPA believes that a uniform method will advance the goals of the Great Lakes Critical Programs Act (CPA). First, EPA believes that the additional protection that the Tier II approach will provide is consistent with the objectives of the Great Lakes Water Quality Agreement, as incorporated into section 118 of the Clean Water Act. Article II of the GLWQA provides that the United States and Canada will make maximum efforts to develop programs, practices and technology necessary for a better understanding of the Great Lakes System, and to eliminate or reduce to the maximum extent practicable the discharge of pollutants into Great Lakes waters. Article III provides general narrative objectives for the Great Lakes System including that the Great Lakes waters should be free from deleterious substances including pollutants that are toxic or harmful to humans, animals or aquatic life. The conservative Tier II

method proposed will contribute to the more rapid achievement of these goals.

Additionally, EPA believes that the Tier II approach is consistent with Congress' goals and objectives. The legislative history of the CPA indicates that Congress recognized that the Great Lakes is both a unique, interconnected ecosystem and a unique National resource that might require unusual measures to protect. See, for example, 136 Cong. Rec. S. 15622–23, Oct. 17, 1990 (Sen. Kohl); S. Rep. No. 101–339, 101st Cong., 2d Sess. at 7. EPA believes that Congress gave EPA discretion to regulate the Great Lakes waters more stringently than other waters of the United States, where a more stringent approach would promote more rapid achievement of desired water quality across the Great Lakes basin. Consequently, EPA is proposing Tier II methods for aquatic life, human health, and wildlife protection that the Initiative Committees developed. Sections D.2 and D.3 below describe the two-tiered approach in more detail.

2. Application of Tier I Methodologies

The proposed Guidance requires Great Lakes States or Tribes to use the Tier I methodologies in appendixes A through D when adopting or revising numeric water quality criteria. In addition, if a Great Lakes State or Tribe has not adopted a numeric water quality criterion for a pollutant in its water quality standards, but enough data exists to meet Tier I minimum data requirements, § 132.4(c) requires use of the Tier I methodologies for any development of numerical criteria to implement narrative criteria. As discussed further below, such implementation would include development of water quality-based effluent limits, where appropriate.

This approach is less flexible than currently allowed under 40 CFR part 131, where States may use EPA's section 304(a) methodologies, or any other scientifically defensible method, in developing numeric criteria and implementing narrative criteria. EPA believes that the proposed approach is desirable and consistent with Congressional intent in order to achieve a greater degree of consistency of water quality-based controls within the Great Lakes System.

The proposed Guidance also includes proposed numeric criteria in Tables 1 through 4 of part 132 that were derived using the Tier I methodologies. EPA is proposing to require Great Lakes States and Tribes to adopt these specific numeric criteria into their water quality standards for the Great Lakes System.

Over time, a database from which both numeric Tier I water quality criteria and Tier II water quality values can be derived will expand. EPA Region 5, in cooperation with Regions 2 and 3, Headquarters offices, and the Great Lakes States and Tribes, will establish a clearinghouse for these environmental data. As additional data become available or additional Tier I numeric criteria and Tier II values are calculated by EPA, States, or Tribes, Region 5 will ensure that this information is disseminated to the Great Lakes States and Tribes. Regions 2, 3 and 5, through their review and approval of State water quality standards under section 303 of the Clean Water Act, will ensure that the Great Lakes States and Tribes maintain the minimum consistent level of protection for aquatic life, human health, and wildlife throughout the Great Lakes System provided by application of the methodologies promulgated in the final Guidance.

The proposed rule does not alter existing regulations under 40 CFR part 131 concerning when a State is obligated to adopt a numeric water quality criterion beyond those specified in Tables 1 through 4 of the proposed Guidance. Section 303(c)(2)(B) currently requires States to adopt numeric criteria for toxic pollutants for which section 304(a) criteria are available, and which could reasonably be expected to interfere with designated uses. EPA regulations do not specify other instances where numeric criteria are required, though EPA has the authority to identify such instances on a case-by-case basis under section 303(c)(4) of the Clean Water Act.

One alternative to the proposed Guidance would be to broaden the States' and Tribes' obligation to adopt numeric Tier I criteria into water quality standards. Specifically, EPA could instead require the Great Lakes States and Tribes to adopt a Tier I criterion into their water quality standards when sufficient toxicological data exists under a Tier I methodology, and when the pollutant could reasonably be expected to interfere with the designated uses in ambient waters, for all pollutants including pollutants for which EPA had not developed National criteria under section 304(a). EPA decided not to propose this alternative, however, because it may increase the administrative burden on Federal, State and Tribal authorities without necessarily providing a significant advantage over EPA's periodic review of State or Tribal water quality standards to determine the need for numeric water quality criteria. Another alternative would be for EPA to amend Tables 1 through 4 in future rulemaking to include additional Tier I criteria as sufficient data become available or are evaluated, and require the Great Lakes States and Tribes to adopt these criteria into their water quality standards. EPA invites comment on these or other alternatives to the proposed Guidance, including the advantages and disadvantages of requiring Great Lakes States and Tribes to adopt any Tier I criterion subsequently calculated or approved by EPA into their water quality standards for the Great Lakes System.

Section 132.4(c) also requires the use of Tier I methodologies when developing numeric criteria to implement State or Tribal narrative criteria if data satisfying the Tier I minimum data requirements are available. For example, if a State or Tribe is deriving numeric criteria for a pollutant to implement the narrative criteria and data are available that meet the minimum data requirements for Tier I, then the State or Tribe must use the Tier I methodologies in the proposed Guidance in deriving the numeric criteria. In this example, because the State or Tribe is not proposing to adopt the numeric Tier I criteria into water quality standards, the State or Tribe does not need to submit the derived numeric criteria to EPA for approval. Instead, the State would use the derived numeric Tier I criteria in developing Total Maximum Daily Loads (TMDLs) and water quality-based effluent limits. In the context of EPA's review and approval of the resulting TMDLs under 40 CFR part 130, and review of the water quality-based effluent limits in NPDES permits submitted under part 123, EPA will review the State and Tribal interpretations of narrative water quality criteria.

EPA invites comments on this approach for the use of Tier I methodologies required under § 132.4(c) and any alternative approaches.

3. Application of Tier II Methodologies

It is preferable, in all cases, to have Tier I criteria available to compute water quality-based effluent limits. However, the development of Tier I criteria is often costly and time consuming. In the absence of a Tier I criterion, the permitting authorities must have some mechanism with which to interpret and ensure that the narrative prohibition against the discharge of toxic substances in toxic amounts is reflected in water quality-based effluent limitations. Options that EPA and the Initiative Committees considered include: a "no data-no discharge" requirement, unless and until Tier I

criteria are established; an ad hoc interpretation of narrative criteria on a case-by-case basis; or a systematic methodology for deriving numbers in the absence of a full database. The Initiative Committees have proposed the latter option—to propose the use of a Tier II methodology to derive values in the absence of data sufficient to develop Tier I criteria. EPA invites comment on this approach, and on the other three options described in this paragraph.

The Tier II approach sometimes requires additional conservatisms, e.g., in the derivation of aquatic life criteria, when the minimum data requirements for Tier I are not met. The approach may therefore result in permit limits which may later be found to be nonresistant than those derived from new toxicity data. In these cases, the cost of complying with the more stringent permit limits may be high because of the additional conservatisms, while the benefits may be low. Of course, one advantage of the Tier II approach is that it ensures that even discharges of pollutants with insufficient data to derive Tier I criteria pose low risks to the environment. EPA solicits comments on identification of any less costly approaches to regulate pollutants for which inadequate data exist to derive Tier I criteria that would fully protect human health, wildlife, and aquatic life in the Great Lakes System.

If a State or Tribe has not adopted a numeric water quality criterion for a pollutant and insufficient data exist to meet Tier I minimum data requirements, proposed § 132.4(c) requires application of Tier II methodologies to develop Tier II values to implement the narrative criteria. Additionally, if sufficient data to calculate a Tier II value for a pollutant on Table 6 of part 132 does not exist, procedure 5 of the Implementation Procedures (appendix F to part 132) requires the permitting authority under specified circumstances to generate or require the permittee to generate the data necessary to derive Tier II values. The requirements in procedure 5 are discussed further in section VIII.E of this preamble.

As described above, the Tier II methodologies generally yield more conservative numbers than Tier I, to reflect the greater uncertainty related to the absence of complete data sets. This creates an incentive on the part of dischargers to generate additional toxicological data. The proposed Guidance recognizes this possibility, and allows dischargers to provide such data. As described in section VIII.I of this preamble, the proposed Guidance provides a reasonable period of time up to two years to provide additional studies necessary to develop a Tier I criterion or to modify a Tier II value. Permittee data must meet the minimum data requirements in the proposed Guidance, including quality assurance requirements. Furthermore, the data are subject to review by the permitting agency.

EPA invites comment on all aspects of this provision including the two-tiered approach for criteria derivation and the use of the specified Tier II methodologies.

In its December 16, 1992, report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," EPA's Science Advisory Board (SAB) expressed concern that anti-backsliding provisions of the Clean Water Act may prevent adjustments in Tier II numbers when more data become available. EPA believes that in most cases the anti-backsliding provisions of the Clean Water Act will not prevent adjustments to either Tier II values or Tier I criteria.

First, under the proposed Guidance anti-backsliding requirements do not apply to changes made in an effluent limitation prior to its compliance date. (See proposed procedure 9, Compliance Schedules, in appendix F to part 132.)

Second, even if anti-backsliding requirements do apply, they may not bar such adjustments. Under section 402(o) of the CWA, relaxation of water quality-based limits is permissible if either the requirements of section 402(o)(2) or section 303(d)(4) are met. These two provisions are independent exceptions to the prohibition against relaxation of permit limits. The exceptions under section 303(d)(4) will, in most cases, provide the flexibility needed for permitting authorities to issue permits reflecting adjustments in Tier I or II numbers. Section 303(d)(4)(A) allows establishment of less stringent water quality-based effluent limits in a permit for discharge into a non-attained water if the existing permit limit was based on a total maximum daily load or other wasteload allocation established under section 303, and attainment of water quality standards is assured. Section 303(d)(4)(B) allows establishment of less stringent water quality-based effluent limits in a permit for discharge into an attained water so long as the revised permit limit is consistent with a State's antidegradation policy, and continues to assure compliance with applicable water quality standards. EPA believes that in most cases where Tier I criteria or Tier II values change as a result of additional data becoming available, discharges will be able to meet the conditions of section 303(d)(4) and therefore not be subject to the prohibition contained in the Clean Water Act.

EPA invites comment on all aspects of the above concerns about the two-tiered approach being proposed, including whether anti-backsliding, antidegradation, or any other provisions or practices may be a significant impediment to adjusting water quality criteria and values when additional data become available, and what alternatives may be available to address the concerns.

E. Applicability of the Water Quality Guidance

This section of the preamble discusses in more detail the applicability of the three major portions of the proposed Guidance.

1. Criteria and Values

a. *Background.* Section 303(c) of the Clean Water Act and implementing regulations at 40 CFR part 131 specify the manner in which EPA and the States or Tribes must review, revise, and adopt water quality standards. Water quality standards include a designated use or uses for the waters of the United States and water quality criteria for such waters based upon the designated uses. In designating uses for a water body, States or Tribes must take into consideration the use and value of water for public water supplies, protection and propagation of fish, shellfish and wildlife, recreation in and on the water, agricultural, industrial, and other purposes including navigation. Section 303(c)(2)(A) of the Clean Water Act; 40 CFR 131.10(a). States or Tribes may designate uses not identified in section 303(c)(2)(A) of the Clean Water Act and 40 CFR 131.10(a) or specify subcategories of uses for particular water bodies, with the exception that no State may designate waste transport or waste assimilation as a use. 40 CFR 131.10(c). Finally, pursuant to section 510 of the Clean Water Act, States or Tribes may designate uses for particular water bodies which require application of more stringent water quality criteria than may be required under the Clean Water Act. In designating uses and establishing appropriate criteria to protect those uses, the States or Tribes must ensure the attainment and maintenance of all downstream water quality standards.

EPA's existing regulations at 40 CFR 131.10(g) authorize States or Tribes to remove certain designated uses of a water body (and establish correspondingly less stringent water quality criteria) upon a demonstration through a use attainability analysis as described in 40 CFR 131.3(g), that

attaining the designated use is not feasible because:

(1) Naturally occurring pollutant concentrations prevent the attainment of the use;

(2) Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the use, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges without violating State water conservation requirements to enable uses to be met;

(3) Human caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place;

(4) Dams, diversions or other types of hydrologic modifications preclude the attainment of the use, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the use;

(5) Physical conditions related to the natural features of the water body, such as the lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of aquatic life protection uses; or

(6) Controls more stringent than those required by sections 301(b) and 306 of the Clean Water Act would result in substantial and widespread economic impact.

Under 40 CFR 131.10(h), however, States or Tribes may not remove designated uses if:

(1) They are existing uses, as defined in § 131.3, unless a use requiring more stringent criteria is added; or

(2) Such uses will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act and by implementing cost-effective and reasonable best management practices for nonpoint source control.

In addition to modifying designated uses for a particular water body, States or Tribes may currently grant temporary variances from water quality standards to point sources based upon any of the six grounds for removing a designated use set forth at 40 CFR 131.10(g). EPA's National policy on variances and the proposed variance procedure for the Great Lakes System are discussed in section VIII.B, below.

b. *Applicability of the Proposed Guidance.* Section 132.4(d) of the proposed Guidance generally requires Great Lakes States or Tribes to apply criteria and values derived from the Tier I and Tier II methodologies for human health, wildlife, and acute and chronic aquatic life to protect all waters of the Great Lakes System. The proposed Guidance does not affect the Great Lakes States' or Tribes' authority under 40 CFR 131.10 to retain, designate or remove uses for portions of the Great Lakes System entirely within their jurisdiction. However, the proposed Guidance differs from current National requirements by generally requiring State and Tribal application of the criteria, values and methodologies in the proposed Guidance to all waters of the Great Lakes System regardless of existing State or Tribal use designations.

There are four exceptions to this general requirement. First, pursuant to section 510 of the Clean Water Act, Great Lakes States or Tribes may apply more stringent numeric criteria or values to any waters of the Great Lakes System within their borders. Second, Great Lakes States or Tribes may develop less stringent site-specific modifications to the criteria and values for aquatic life for specific waters of the Great Lakes System in certain limited circumstances. However, any such site-specific modifications must still be protective of aquatic life. This provision is discussed in section VIII.A, below.

Third, with regard to human health, the methodology in appendix C produces criteria and values under two sets of exposure assumptions. The methodologies for deriving "Nondrinking" criteria and values assume that humans are exposed to pollutants in the Great Lakes System via two routes: incidental consumption of water as a result of recreational activities in the Great Lakes System; and consumption of fish that have accumulated pollutants in their tissue. The methodologies for deriving "Drinking" criteria and values assume that, in addition to these two exposure routes, humans are also exposed to pollutants from the Great Lakes System as a result of direct use of the waters without treatment for drinking water purposes. The "Drinking" criteria and values are generally more stringent than the "Nondrinking" criteria and values, because of the additional route of exposure. Section 132.4(d)(3) of the proposed Guidance specifically provides that the criteria and values derived using the "Drinking" assumptions shall apply to the open waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated for use as public water supplies by any Great Lakes State or Tribe in accordance with 40 CFR 131.10(a). Criteria and values derived using the "Nondrinking" assumptions are proposed to apply to all other waters of the Great Lakes System.

Fourth, § 132.4(g) provides that Great Lakes States and Tribes are not required to use the proposed criteria development methodologies or implementation procedures for pollutants listed in Table 5 of the proposed Guidance, or upon demonstration that application of one or more methodologies or procedures to the pollutant is not scientifically defensible. The rationale for these exclusions is discussed in section II.F of this preamble.

Finally, upon incorporation into enforceable State, Tribal, or Federal laws, the criteria and values or appropriate site-specific modifications developed under the proposed Guidance will apply to a wide range of regulatory decisions, including decisions under statutes other than the Clean Water Act. Examples of such application include:

i. Issuance of NPDES permits pursuant to section 402 of the Clean Water Act or consistent provisions of State law;

ii. Issuance of permits authorizing the discharge of dredged and fill material pursuant to section 404 of the Clean Water Act or consistent provisions of State law;

iii. Development of Lakewide Management Plans and Remedial Action Plans pursuant to section 118(c)(4) of the Clean Water Act, as amended by the Great Lakes Critical Programs Act of 1990;

iv. Promulgation of emission standards and control measures necessary to prevent widespread environmental or serious adverse public health effects from atmospheric deposition of air pollutants to the Great Lakes pursuant to section 112(m) of the Clean Air Act, as amended by the Clean Air Act Amendments of 1990;

v. Determination of applicable or relevant and appropriate requirements (ARARs) under section 121 of the Comprehensive Environmental Response, Compensation and Liability Act of 1980; and

vi. Determination of corrective action requirements under sections 3004(u), 3008(h), or 7003 of the Solid Waste Disposal Act or consistent provisions of State law.

c. *Justification for the Proposed Approach.* The requirement set forth in the proposed Guidance that the criteria and values generally apply throughout the Great Lakes System regardless of use designations is more restrictive than current National policy. EPA believes that this more restrictive approach is necessary for the Great Lakes System for several reasons.

First, as explained in section I above, EPA believes that the Great Lakes are an integrated ecosystem requiring a consistent approach to pollution control across the entire basin. Allowing Great Lakes States and Tribes to retain the broad discretion that they possess under

the current National program would seriously hinder—and perhaps prevent—the attainment of the goals of the Great Lakes Critical Programs Act amendments to section 118 of the Clean Water Act.

One of the most important goals of this legislation was the establishment of more uniform control of pollution throughout the Great Lakes System. This theme appears in both the House and Senate Committee reports. See H.R. 101–704, 101st Cong., 2d Sess. at 8 (Sept. 14, 1990); S. 101–339, 101st Cong. 2d Sess. at 12, 18 (June 27, 1990). It is also a common thread in the floor statements of nearly all of the individual members of Congress that addressed the House and Senate bills. See, e.g., 136 Cong. Rec. H 7918 (Sept. 24, 1990) (remarks of Rep. Roth); 136 Cong. Rec. H 12325 (Oct. 27, 1990) (remarks of Rep. Stangeland); 135 Cong. Rec. S 1153 (Sept. 20, 1989) (remarks of Sen. Levin); 136 Cong. Rec. S 15620, 15623 (Oct. 17, 1990) (remarks of Sen. Levin and Sen. Kohl). The proposed Guidance, by generally requiring application of the criteria and values derived from the Tier I and Tier II methodologies for human health, wildlife, and acute and chronic aquatic life to all waters of the Great Lakes System (unless a State or Tribe successfully shows the need for a site-specific modification to the aquatic life criteria and values) will promote this goal.

Further, the legislative history shows that Congress was aware of the Great Lakes States' Water Quality Initiative and viewed this effort with approval. See S. Rep. 101–339, 101st Cong., 2d Sess. at 18 (June 27, 1990); 136 Cong. Rec. S 15620 (Oct. 17, 1990) (remarks of Sen. Levin). Because the achievement of consistent water quality was the key goal of the Initiative, it is reasonable to assume that Congress endorsed the same goal.

Third, a primary impetus behind the initial creation of the Great Lakes Water Quality Initiative was the 1986 Great Lakes Toxic Substances Control Agreement ("Governors' Agreement"). In that Agreement, the Governors of the eight Great Lakes States "commit[ted] to managing the Great Lakes as an integrated ecosystem, recognizing that the water resources of the Basin transcend political boundaries." The Governors' Agreement explained that such an ecosystem-based approach is necessary because:

> [t]he relatively closed nature of the system makes the Great Lakes especially vulnerable to pollution. Consequently, the actions of one jurisdiction or user in the system may have an impact on others. Because of this interdependence and the resource's economic and social value to the region, it is crucial that the lakes be managed as an integrated system.

The Governors' Agreement also recognized that uniform water quality standards should be developed for pollutants of concern in the Great Lakes System to avoid "costly duplication of research and standardsetting." Finally, the Governors' Agreement recognized that "[m]aintaining and improving the quality of Great Lakes waters will sustain water supply systems and commercial, manufacturing and recreation industries, while creating new economic development opportunities."

Section 132.4(d) of the proposed Guidance implements the principles of the Governors' Agreement and reflects the proposal of the Great Lakes Steering Committee to require the Great Lakes States to generally apply numeric criteria and values equal to or more stringent than the Tier I criteria and Tier II values throughout the Great Lakes System, with the limited site-specific exceptions discussed in section VIII.A, below. This requirement is intended to result in the development of more uniform water quality standards throughout the Great Lakes System and a reduction in costly duplication of research and standard-setting by the Great Lakes States and Tribes.

Finally, the legislative history also shows strong Congressional intent to implement portions of the 1978 Great Lakes Water Quality Agreement relating to water quality standards, antidegradation policies, and implementation procedures. See, e.g., H.R. Rep. 101–704, 101st Cong., 2d Sess. at 2, 8 (Sept. 14, 1990); 136 Cong. Rec. H 7916 (Sept. 24, 1990) (remarks of Rep. Nowak); 136 Cong. Rec. S 15620, 15623 (Oct. 17, 1990) (remarks of Sen. Levin and Sen. Kohl). Moreover, Congress interpreted the Agreement as requiring uniform water quality "throughout the Great Lakes." 136 Cong. Rec. S 15620 (Oct. 17, 1990) (remarks of Sen. Levin).

The rationale for the human health methodology deserves additional discussion. The methodologies for deriving "Nondrinking" criteria and values assume that humans are exposed to pollutants in the Great Lakes System via two routes: incidental consumption of water as a result of recreational activities in the Great Lakes System; and consumption of fish that have accumulated pollutants in their tissue. The methodologies for deriving "Drinking" criteria and values assume that, in addition to these two exposure routes, humans are also exposed to pollutants from the Great Lakes System as a result of direct use of the waters without treatment for drinking water purposes. Because of this additional route of exposure, the "Drinking" criteria and values generally will be more stringent than those for "Nondrinking."

The requirement in § 132.4(d)(3)(ii) of the proposed Guidance regarding the applicability of the "Nondrinking" criteria and values is based upon two conservative assumptions. First, EPA is assuming that humans use all waters of the Great Lakes System for recreational purposes, regardless of any applicable use designations. Second, EPA is assuming that humans consume aquatic life that swim through or live in (and therefore have accumulated pollutants from) all waters of the Great Lakes System. Consequently, EPA is assuming that humans may be exposed to pollutants from any water of the Great Lakes System via either of the first two routes of exposure described above. To the extent that these assumptions are inaccurate, they err on the side of being overprotective of human health rather than underprotective. Moreover, this approach will promote consistent application of criteria and values throughout the Great Lakes System, thereby furthering one of the primary goals of the Great Lakes Critical Programs Act. Finally, this approach is consistent with the proposal of the Steering Committee. EPA requests public comment on these assumptions.

Section 132.4(d)(3)(i) of the proposed Guidance requires application of the "Drinking" criteria and values to open waters of the Great Lakes, the connecting channels, and all other waters designated for use as public water supplies. During the Great Lakes Water Quality Initiative process, it was suggested that because it is unlikely that drinking water intakes will be located behind constructed breakwalls, there is no need to apply the "Drinking" criteria and values to waters that are located behind constructed breakwalls. The proposed Guidance does not allow this exception for two reasons.

First, 40 CFR 131.11(a) requires that "States must adopt those water quality criteria that protect the designated use." The "Drinking" criteria and values are designed to protect humans from suffering adverse health effects from drinking water; that is, they are designed to protect public water supply uses. All of the open waters of the Great Lakes have been designated for public water supply uses. The proposed exception for waters located behind constructed breakwalls, to the extent it would allow application of water quality criteria that are less stringent than the "Drinking" criteria and values

in waters that have been designated for use as public water supplies, is not consistent with 40 CFR 131.11(a).

Second, to the extent that States or Tribes believe that certain waters of the Great Lakes System have not and will not be used for public drinking water supplies, they may seek to change the use designation of such segments consistent with EPA regulations in 40 CFR part 131.10. Notwithstanding any such changes, of course, regulatory authorities issuing NPDES permits must insure that point source discharges will not interfere with attainment of all downstream water quality standards. Consequently, when establishing controls on discharges of pollutants into waters of the Great Lakes System that have not been designated for use as public water supplies, Great Lakes States and Tribes must consider any effects that such discharges will have on waters of the Great Lakes System that have been designated for use as public water supplies.

The approach taken in the proposed Guidance regarding the applicability of criteria and values for human health ensures that water quality criteria shall be applied to protect human health throughout the Great Lakes System. EPA recognizes that this approach is more restrictive than EPA's current National policy. However, as explained above, EPA believes that general application of all criteria and values throughout the entire Great Lakes System is required to promote consistent water quality standards in the Great Lakes System.

EPA requests comment on the proposed provision generally requiring basin-wide application of the Tier I criteria and Tier II values regardless of existing use designations. EPA believes that the use designations for most waters within the Great Lakes System currently include protection of aquatic life and recreational uses. EPA recognizes, however, that there are a few waters within the Great Lakes System that are not currently designated to protect these uses. EPA requests comment on all aspects of this issue including the proposed applicability provisions, the exceptions discussed above, and any suggested alternatives.

d. *Other Options Considered.* The Steering Committee believed that the Great Lakes States and Tribes should be allowed to apply criteria and values other than the Tier I criteria and Tier II values for chronic aquatic life when justified through a use attainability analysis pursuant to 40 CFR part 131. The Steering Committee also believed that this exception should be limited to application of criteria and values for pollutants that are not bioaccumulative chemicals of concern (BCCs). The Steering Committee developed this exception because the chronic aquatic life methodologies are based on exposures of 96 hours and there may be sites within the Great Lakes System where physical and hydrologic conditions preclude aquatic life from remaining in the particular site for that time period. Therefore, some members of the Steering Committee believed that uniform application of the criteria and values for chronic aquatic life health would be more stringent than necessary to protect aquatic life in those specific sites.

EPA has decided to address this issue in procedure 1 of appendix F of the proposed Guidance on site-specific modifications, rather than in § 132.4 on applicability. EPA's existing regulations allow modification of designated uses based on the factors specified in 40 CFR 131.10(g). Because the stringency of water quality criteria that must be applied to a water body under EPA's current National regulations is dependent upon the use that is designated for the water body, a modification of a use pursuant to 40 CFR 131.10(g) may allow for application of less stringent criteria.

As explained above, however, the proposed Guidance differs from EPA's current National regulations in that the proposed Guidance generally requires application of water quality criteria and values throughout the Great Lakes System that will be protective of human health, wildlife and aquatic life, regardless of State or Tribal use designations. In light of this approach, EPA believes that exceptions from the requirement to apply the criteria and values for aquatic life may be equally but more appropriately addressed in procedure 1 of appendix F on site-specific modifications. Procedure 1 of appendix F proposes a procedure by which States or Tribes may develop site-specific modifications to the criteria and values derived from the Great Lakes methodologies for chronic aquatic life to reflect local hydrologic and physical conditions within the Great Lakes System. However, EPA specifically invites comment on the alternative approach to address these site-specific conditions through use attainability analyses and whether State or Tribal use designations should play a more prominent role in the Great Lakes System than is envisioned by the proposed Guidance.

2. Implementation Procedures

a. *Applicability of the Proposed Guidance.* Section 132.4(e) of the proposed Guidance requires States to apply the implementation procedures set forth in appendix F "in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source," with two exceptions. First, under § 132.4(e)(1), Great Lakes States and Tribes are not required to apply any of the proposed Implementation Procedures to wet-weather discharges. Second, under § 132.4(e)(2), Great Lakes States and Tribes have discretion to decide whether to apply procedures 1, 2, 3, 4, 5, 7, 8 and 9 to establish controls on the discharge of any pollutant set forth in Table 5. However, regulatory authorities must apply the whole effluent toxicity (WET) requirements set forth in procedure 6 in establishing controls on the discharge of all effluents to the Great Lakes System. Section 132.4(e)(2) provides that any implementation procedures adopted by a Great Lakes State or Tribe shall conform with all applicable Federal, State, and Tribal requirements.

b. *Justification for the Proposed Approach.* The proposed Guidance generally requires application of the Implementation Procedures set forth in appendix F throughout the Great Lakes System. As discussed in sections I and II.E.1 of this preamble, this condition is necessary to implement the primary goal of the CPA—to establish a more uniform level of water quality control throughout the Great Lakes System.

The proposed Guidance provides exceptions in two situations: In establishing controls on the discharge of pollutants by wet-weather point sources; and in establishing controls on the discharge of any pollutant identified in Table 5, or any other pollutant for which the Great Lakes State or Tribe demonstrates that one or more methodologies or procedures are not scientifically defensible. The justification for each exception is discussed below.

i. *Wet-weather Point Source Discharges.* Section 132.4(e)(1) of the proposed Guidance provides that the Great Lakes States and Tribes are not required to apply the proposed Implementation Procedures in establishing water quality-based controls on wet-weather point source discharges to the Great Lakes System. A wet-weather point source is defined in § 132.2 of the proposed Guidance as

> a point source which is either an outfall from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8), a storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14), or a combined sewer overflow. A combined sewer overflow is a flow from a combined sewer in excess of the interceptor or regulator capacity

which is discharged into a receiving water body without going to a publicly owned treatment works. Combined sewer overflows occur prior to the headworks of a treatment facility. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet-weather point source.

EPA believes that allowing the States and Tribes the discretion to apply the proposed procedures in wet-weather situations on a site-specific basis where appropriate is necessary due to the significant differences that exist between wet-weather point source discharges and dry-weather point source discharges. For example, in order to implement water quality standards for a particular pollutant in a particular receiving water, it is necessary to account for a variety of conditions including the rate, volume and duration of effluent flow into the receiving water; the nature and volume of pollutants in the effluent; the flow rate and volume of the receiving water; and the background concentrations of pollutants in the receiving water. Because these conditions remain fairly constant during dry-weather periods, EPA has been able to develop general guidance on many implementation procedures that can be applied to most point source discharges. See, e.g., "Technical Support Document for Water Quality-based Toxics Control" (1991); "Technical Guidance of Supplemental Stream Design Conditions for Steady State Modeling" (1989); "Technical Guidance Manual for Performing Waste Load Allocations, Book II Streams and Rivers, Chapter 3 Toxic Substances" (1984); "Water Quality Standards Handbook" (1983).

The conditions associated with wet-weather point source discharges, in contrast, are intermittent and occur during and immediately following wet-weather events. Consequently, the rate and volume of flow in the receiving water may rapidly fluctuate during such discharges. Furthermore, the degree of fluctuation of pollutants within the receiving water also may vary depending on a wide range of factors including the magnitude and duration of and time period between rainfall events; the amount and flow of storm water being discharged as compared to the amount and flow of the receiving water; the soil conditions and land use activities near the receiving water; and the degree to which land near the receiving water is impervious to precipitation. See 55 FR 47990, 48038 (Nov. 16, 1990); 53 FR 49416, 49444 (Dec. 7, 1988).

A second cause of the variability associated with wet-weather is that much of the effluent discharged during wet-weather consists of storm water run-off containing pollutants whose source, nature, and extent varies according to local land use activities as well as the other factors described above that cause variability in receiving waters. See 55 FR 48038, 49443 (Nov. 16, 1990). Discharges from combined sewer overflows, for example, include pollutants from domestic waste such as bacteria, nutrients, BOD, solids and floatables which, due to the intermittent nature of storm events, are intermittently discharged in combined sewer overflows and in storm water and can vary considerably.

Due to the high degree of variability associated with wet-weather conditions, EPA has not developed a general set of implementation procedures for uniform application to all wet-weather point source discharges. Instead, EPA's National policy has been to allow permitting authorities familiar with local wet-weather conditions to establish site-specific controls on wet-weather point source discharges to implement technology-based requirements based on the permitting authorities' best professional judgment and to meet water quality standards. See National Combined Sewer Overflow Strategy, 54 FR 37370 (September 8, 1989). However, permittees with combined sewer overflows generally are expected to implement the nine minimum controls listed in EPA's draft Combined Sewer Overflow Control Policy (see 58 FR 4994 (January 19, 1993)), and to achieve volume or mass reductions, overflow restrictions or other limits as necessary to achieve water quality standards. EPA believes that the variability associated with wet-weather point source discharges on a National level is also present with regard to wet-weather point source discharges into the Great Lakes System. Consequently, consistent with EPA's National policy, the proposed Guidance does not require but allows the Great Lakes State or Tribe discretion to apply any of the proposed procedures in establishing controls on wet-weather point source discharges on a site-specific basis.

Although EPA is not proposing to require the Great Lakes States or Tribes to apply any of the proposed Implementation Procedures to wet-weather point source discharges, EPA believes that some of these procedures could technically be applied to establish controls on wet-weather point source discharges. For example, the proposed procedures for variances could be applied to both dry-weather and wet-weather point source discharges. In contrast, the proposed procedure for determining reasonable potential to exceed water quality-based effluent limitations may not be fully applicable to wet-weather discharges. This is because the statistical methods set forth in the procedure are based on the assumption that the effluent concentration and receiving water flow behave independently; that is, for dry-weather discharges, there is an equal likelihood that a high or low effluent concentration could occur at any receiving water flow. However, in the case of wet-weather, both the effluent concentration and receiving water flow are influenced by rainfall and therefore do not always behave independently. EPA requests comment on all aspects of this proposed exclusion for wet-weather discharges including: the appropriateness of the proposed exclusion for wet weather discharges; the definition of wet-weather point sources; which implementation procedures could appropriately be applied in establishing regulatory controls on wet-weather point source discharges; and whether the final rule should require permitting authorities to apply any particular procedures in establishing controls on wet-weather discharges in the Great Lakes System.

Section 132.4(e)(1) of the proposed Guidance requires that "any procedures applied in lieu of these implementation procedures shall be consistent with all applicable Federal, State, and Tribal requirements." Accordingly, even though permitting authorities are not required to apply the Great Lakes Implementation Procedures in establishing controls on wet-weather point source discharges, all permits must still contain any limitations and conditions necessary to ensure compliance with the Clean Water Act and implementing Federal and State regulations. Furthermore, under §§ 132.3 and 132.4(c) of the proposed Guidance, all criteria and values and site-specific modifications thereof apply for all purposes specified in the Clean Water Act for criteria developed under section 304(a), including decision-making regarding wet-weather point source discharges.

As part of EPA's National activities regarding combined sewer discharges, EPA is evaluating whether the present assumptions used in the water quality criteria, water quality standards, total maximum daily load/waste load allocation, and permitting processes are appropriate for wet-weather discharges. Upon completion of this evaluation, EPA intends to issue guidance either affirming the scientific validity of those present assumptions that it determines are appropriate for wet-weather

discharges or, where present assumptions are not appropriate, modifying the assumptions as necessary to account for wet-weather situations. Additionally, as discussed in section I.G. of this preamble, EPA has convened a separate multimedia work group (the Great Lakes Toxics Reduction Initiative) to determine whether additional guidance for the Great Lakes System should be developed in several areas, including specific implementation guidance for wet-weather point and nonpoint source discharges. In the event that uniform National procedures or guidance to implement water quality standards in permits are developed specifically for wet-weather point source discharges, EPA will evaluate the appropriateness of application of such procedures to the Great Lakes System.

ii. *Excluded Pollutants.* Section 132.4(g) provides that States and Tribes are not required to use the proposed Implementation Procedures to develop water quality-based effluent limits for a pollutant if it is listed in Table 5 of the proposed Guidance, or if the State or Tribe demonstrates that applying one or more methodologies or procedures to the pollutant is not scientifically defensible. EPA recognizes that some of the Great Lakes Implementation Procedures in appendix F could technically be applied in establishing controls on the discharge of some or all of the pollutants listed in Table 5. For example, procedure 2 (Variances from Water Quality Standards) could be applied in determining whether to grant a variance from water quality standards to a point source discharger of any pollutant.

Nevertheless, § 132.4(e)(2) of the proposed Guidance provides that, with the exception of procedure 6 (Whole Effluent Toxicity Requirements for Point Sources), the Great Lakes States and Tribes may, but are not required to, apply the proposed Implementation Procedures in establishing controls on the discharge of any pollutant set forth in Table 5 of the proposed Guidance. The rationale for requiring whole effluent toxicity testing for all discharges, including those containing Table 5 pollutants, is discussed in section VIII.F, below. Table 5 contains sixteen pollutants: Alkalinity, ammonia, bacteria, biochemical oxygen demand, chlorine, color, dissolved oxygen, dissolved solids, hydrogen sulfide, pH, phosphorus, salinity, sulfide, temperature, total and suspended solids, and turbidity. The basis for the general exception for Table 5 pollutants, including the rationale for selection of the pollutants, is discussed in section II.F of this preamble. The exclusion of additional pollutants on the basis of scientific defensibility is also discussed in section II.F.

EPA specifically requests comment on: Today's proposed approach to allow States and Tribes the flexibility to select implementation procedures for Table 5 pollutants as long as they are consistent with Federal, State, and Tribal requirements; which of the Great Lakes Implementation Procedures could be applied in establishing regulatory controls on the discharge of any or all of the pollutants listed in Table 5; and whether regulatory authorities should be required to apply any or all of the Great Lakes implementation procedures in establishing controls on the discharge of any or all of the pollutants listed in Table 5. EPA also invites comment on the 132.4(g) exclusion for scientific defensibility as applied to the Implementation Procedures in appendix F, discussed further in section II.F, below.

3. Antidegradation Policies

The proposed Guidance requires Great Lakes States and Tribes to apply the antidegradation policy adopted pursuant to § 132.4(a)(6) for all applicable purposes under the Clean Water Act, including 40 CFR 131.12, for all pollutants. Unlike other parts of the proposed Guidance, which focus on regulatorily determined desirable levels of water quality, the antidegradation policy focuses on actual water quality. Traditionally, antidegradation policies have operated independently of, or as a backstop to, individual water quality criteria adopted to protect particular uses. Hence, the reasons for distinguishing between particular pollutants for purposes of prescribing methodologies for criteria development do not appear particularly relevant to the question of the applicability of the antidegradation policy. EPA requests comments on the proposal to make appendix E applicable to all pollutants.

F. Excluded Pollutants

The proposed Guidance generally requires application of the criteria development methodologies in appendixes A, B, C and D, and the Implementation Procedures in appendix F for all pollutants except for the 16 pollutants listed in Table 5 and any pollutant other than those in Table 5 for which the Great Lakes State or Tribe demonstrates that application of one or more guidance procedures to the given pollutant are not scientifically defensible. The pollutants listed in Table 5 are: alkalinity, ammonia, bacteria, biochemical oxygen demand (BOD), chlorine, color, dissolved oxygen, dissolved solids, hydrogen sulfide, pH, phosphorus, salinity, sulfide, temperature, total and suspended solids, and turbidity.

With regard to the exclusion of pollutants in Table 5, the States and EPA have had many years of extensive experience in control of these pollutants. For example, regulatory and voluntary programs to control phosphorus began in the 1960s and continue to the present. Additionally, all of the Great Lakes States have adopted, and EPA has approved, numeric water quality criteria for these pollutants. Based on this extensive experience, the Steering Committee of the Great Lakes Water Quality Initiative believed that efforts should not be made to develop criteria, methodologies, and implementation procedures that could uniformly be applied to these pollutants given the limited time and resources available to complete the work of the Initiative.

Based on these considerations, the Initiative Committees believed that regulatory authorities should retain the flexibility in their existing water quality programs to address these pollutants on a site-specific basis. EPA believes that the existing EPA-approved State water quality standards for these pollutants are adequate to protect aquatic life, human health, and wildlife in the Great Lakes System. Although variations do exist in the criteria and implementation procedures for these pollutants in the Great Lakes States, EPA also believes that the variability is not sufficient to adversely affect the protection of aquatic life, human health, or wildlife in the Great Lakes System because of the extensive experience of EPA and the States in the regulation of these pollutants.

Additionally, uniform application of the methodologies and implementation procedures is not appropriate for some of the excluded pollutants in Table 5 because of technical reasons. For example, modifications to the proposed criteria development methodologies would be required to derive criteria or values for alkalinity and color. Given the limited time and resources available to derive these additional methodologies and the extensive regulatory experience in controlling these parameters, EPA believes that the existing State and Federal requirements should continue to be used for these pollutants.

EPA may consider expanding the methodologies and procedures to specifically address these pollutants in the future, and invites comment on: Whether the final rules should require some or all of the proposed Guidance or

alternative requirements to be applied to any of the identified pollutants; and identification of any modifications that would be necessary to apply the proposed methodologies or procedures to any of these pollutants.

EPA recognizes that some of the excluded pollutants are identified in Annex 1 of the Great Lakes Water Quality Agreement (GLWQA). As discussed in sections I and III.D.1.b, EPA has indicated its intention to seek modifications to the GLWQA, where necessary, to specify criteria and procedures for these pollutants that are scientifically based and protective of aquatic life, human health and wildlife in the Great Lakes System.

Section 132.4(g) also provides that the Great Lakes States and Tribes may but are not required to, apply the proposed criteria methodologies and implementation procedures to any pollutant for which the regulatory authority demonstrates that one or more procedures in the Guidance are not scientifically defensible. The reason for this exclusion is that there may be pollutants identified in the future for which some of the methodologies or procedures being proposed today may not be technically appropriate. Under these circumstances, EPA wishes to provide sufficient flexibility for permitting authorities to address these pollutants on a case-by-case basis.

The exclusion related to scientific defensibility may be used by a Great Lakes State or Tribe either when developing numeric water quality criteria, interpreting narrative criteria, or implementing narrative or numeric criteria in individual NPDES permits. For example, if a Great Lakes State or Tribe determines that a procedure for modifying a water quality criterion is not scientifically defensible when applied to a specific pollutant, they would provide the demonstration described in § 132.4(g) in their submission of the new or revised criteria to EPA under section 303(c)(2)(A) of the Clean Water Act. If the issue arises during development of a TMDL based on interpretation of a narrative criterion, the Great Lakes State or Tribe could provide the demonstration at the time a TMDL developed pursuant to procedure 3 is submitted to EPA for review. Similarly, if the Great Lakes State or Tribe determines that an alternative implementation procedure is necessary to develop water quality-based effluent limits in an individual permit to implement narrative or numeric criteria for a particular pollutant based on this exclusion, they would submit the supporting demonstration for EPA review as part of the submitted TMDL or proposed NPDES permit. These demonstration submissions should include: Identification of the provision of the proposed Guidance that the regulatory authority has not applied to a pollutant; demonstration that application of the provision to the pollutant is not scientifically defensible; and a description of the scientifically defensible alternative method to be used in place of the provision in the proposed Guidance.

EPA invites comment on all aspects of the exclusion in § 132.4(g), including whether the final Guidance should specify minimum requirements for use of this exclusion, demonstration elements, or procedures for EPA review of these submissions.

G. Pollutants of Initial Focus for Criteria Development, and Bioaccumulative Chemicals of Concern

The Guidance being proposed today, while generally applying to all pollutants (except for the pollutants in Table 5 for some provisions), was structured to provide an initial focus on 138 pollutants listed in Table 6. The pollutants listed in Table 6 were identified by the Steering Committee to be those known or suspected of being of primary concern in the Great Lakes basin. Table 6 is composed of:

1. The 126 pollutants that have been identified by EPA as priority toxic pollutants. The listing appears as appendix A of 40 CFR part 423. The priority pollutant list identifies toxic pollutants of concern on a National basis. It has served as a basis for numerous EPA actions, including: the selection of pollutants for development of water quality criteria under section 304(a) of the Clean Water Act; the development of technology-based effluent guidelines under section 301 of the Clean Water Act; the listing of impaired waters under section 304(l) of the Clean Water Act; and as a basis for determining State compliance with section 303(c)(2)(B) of the CWA which requires States to adopt numeric criteria for toxic pollutants of concern in State waters.

2. Pollutants listed in the Great Lakes Water Quality Agreement of 1978 (as amended by the Protocol signed November 18, 1987). The Agreement identifies pollutants of concern in the Great Lakes System or parts thereof. Specifically, Table 6 of the proposed Guidance includes most of the pollutants for which there are "Specific Objectives" in Annex 1 of the Agreement. However, Table 6 excludes 16 of the entries in Annex 1: eight are pollutants contained in Table 5 of the proposed Guidance and were omitted for the reasons discussed in section II.F of this preamble. Examples in this group include total dissolved solids, pH, and temperature. The remaining eight entries in Annex 1 were omitted because they did not list specific pollutants by name, but rather identified undifferentiated groupings of pollutants that could not be used to establish a meaningful focus for individual pollutants in the Great Lakes Water Quality Initiative. Examples in this group include "unspecified organic compounds," "other pesticides," and "unspecified non-persistent toxic substances and complex effluents."

3. Pollutants categorized as IA or IB in the Categorization of Toxics in Lake Ontario (July 1988) under the Lake Ontario Toxics Management Plan, or in the Categorization of Toxic Substances in the Niagara River (June 1990) under the Niagara River Toxics Management Plan. The Lake Ontario and Niagara River Toxics Management Plans identify pollutants of concern in a specific Great Lake or in a connecting channel plan, that may also be of concern in upstream lakes or connecting channels. Category IA and IB pollutants are those pollutants for which ambient data are available and an enforceable (IA) or unenforceable (IB) standard is exceeded.

4. Pollutants included on a case-by-case basis. Table 6 includes three pollutants solely on this basis: Malathion; 2,4-D (2,4-Dichlorophenoxyacetic Acid); and Chlorpyrifos. EPA has developed National water quality criteria guidance documents for the protection of aquatic life for these pollutants: ambient water quality criteria for Malathion and 2,4-D were published in "Quality Criteria for Water" ("Red Book"), U.S. EPA, 1976 (PB–263943). Ambient water quality criteria for Chlorpyrifos were published at 51 FR 43666 (December 3, 1986). These commonly used pesticides or herbicides were included in Table 6 because of their known or suspected presence or widespread use in the Great Lakes System.

The primary purpose of the Initiative Committees in specifying pollutants in Table 6 was to provide an initial focus for criteria development and the calculation of bioaccumulation factors in the Great Lakes System. The pollutants included in Table 6 were not intended to be a comprehensive inventory of all pollutants present, used or manufactured in the Great Lakes System. If the listing included as Table 6 was to become such an exhaustive inventory, it would not be useful for providing this initial focus.

The proposed Guidance provides an initial focus on the Table 6 pollutants in the following three ways. First, the pollutants for which EPA and the States have applied the proposed criteria methodologies to derive numeric water quality criteria—that is, the pollutants in Tables 1, 2, 3 and 4—were selected from the list of pollutants in Table 6. EPA and the Initiative Committees believe that the pollutants for which EPA establishes minimum water quality standards, as required by the Great Lakes Critical Programs Act of 1990, should, as a minimum, include those known or suspected of being of primary concern in the Great Lakes basin—that is, those in Table 6. In selecting from the Table 6 pollutants for which numeric water quality criteria would be calculated for inclusion in the proposed Guidance, EPA and the Initiative Committees considered a number of factors in addition to those used to develop Table 6. These other factors, described in sections III, V and VI of this preamble, include data availability, chemical characteristics, and environmental effect on the Great Lakes System.

Second, EPA and the Great Lakes States limited calculation of human health bioaccumulation factors (BAFs) for the proposed Guidance to Table 6 pollutants. BAF calculation is necessary when developing water quality criteria to protect human health and wildlife. The BAFs calculated for use in the proposed Guidance will facilitate State and Tribal development of such criteria. In developing Table 6, EPA and Initiative participants developed human health BAFs for each of the 138 pollutants. These BAFs are described in the technical support document, "Derivation of Proposed Human Health and Wildlife Bioaccumulation Factors for the Great Lakes Initiative," available in the administrative record for this rulemaking. Copies are also available as described in section III of this preamble. BAF calculation is also necessary to determine bioaccumulative chemicals of concern (BCCs), which are discussed below.

The third way that Table 6 affects the initial focus of this Guidance is in determining when States, Tribes, and/or permitters must generate data necessary to calculate Tier II values used in developing water quality-based effluent limits. Procedure 5.D of the proposed Implementation Procedures in appendix F requires that permitting authorities generate, or have permitters generate, the data necessary to calculate Tier II values for pollutants in Table 6 for which there is no Tier I criterion or Tier II value if the permitting authority determines based on a specified screening approach that a discharge causes, has the reasonable potential to cause or contributes to an excursion above a State water quality standard.

EPA invites comment on the listing of pollutants contained in Table 6 and on the basis for including pollutants in Table 6. EPA also invites comment on whether pollutants should be deleted from Table 6 or added to Table 6, including the pollutants listed in the Great Lakes Water Quality Agreement, Annex 10, Appendix 1 (Hazardous Polluting Substances) or Appendix 2 (Potentially Hazardous Polluting Substances) or pollutants categorized as ID or IE in the Categorization of Toxics in Lake Ontario or in the Categorization of Toxic Substances in the Niagara River. Category ID pollutants are those pollutants for which ambient data are available but for which a complete categorization was not possible due to detection limits. Category IE pollutants are pollutants for which ambient data are available but no criterion is known to be available.

EPA also invites comment on whether the requirements in implementation procedure 5.D should be focused on a limited list of pollutants, such as the 138 pollutants in Table 6 or whether Procedure 5.D should be extended to apply to any other pollutants for which water quality criteria or values are not available.

As discussed in more detail in sections I.A and I.D of this preamble, the Initiative Committees were particularly concerned about pollutants which exhibited system-wide impacts, such as mercury and PCBs, due to their propensity to bioaccumulate in the food chain and/or persist throughout the Great Lakes System. The Steering Committee wanted to prevent additional chemicals with similar tendencies from reaching levels that would also impact the Great Lakes System. The Technical Work Group recommended utilizing a bioaccumulation factor methodology which incorporates metabolism and other physicochemical properties as a mechanism by which to identify highly bioaccumulative chemicals which could cause system-wide impairments of beneficial uses. The Steering Committee selected a bioaccumulation factor (BAF) of 1000 as an indicator of a pollutant's ability to be highly bioaccumulative. A pollutant with a BAF greater than 1000 was believed by the Steering Committee to have a high potential to be found in aquatic organisms of the Great Lakes System and therefore to have the potential to cause a significant risk to the health of the aquatic life and consumers of the aquatic life such as wildlife and humans inhabiting the Great Lakes basin. Those pollutants with a bioaccumulation factor greater than 1000, after considering metabolism and other properties, are called bioaccumulative chemicals of concern (BCCs) in the proposed Guidance. BCCs are subject to more stringent controls than other chemicals, as explained in section I.D of this preamble. The Guidance (in § 132.2) defines BCCs as follows:

> Bioaccumulative chemical of concern (BCC) is any chemical which, upon entering the surface waters, by itself or as its toxic transformation product, bioaccumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B to part 132. BCCs include, but are not limited to the pollutants identified as BCCs in Table 6.

As described above, EPA and the Initiative Committees developed BAFs for each of the 138 pollutants in Table 6. Thirty-eight (38) pollutants were found to have BAFs greater than 1000 under the assumption of 5.0 percent lipid content that is used for human health criteria development. For ten of these 38 pollutants, however, EPA believes the BAF may need to be adjusted in accordance with section VI.D.5 of the Methodology for Development of Bioaccumulation Factors in appendix B, which states:

> 5. Both human health and wildlife BAFs should be reviewed for consistency with all available data concerning the bioaccumulation of the chemical. In particular, information on metabolism, molecular size, or other physicochemical properties which might enhance or inhibit bioaccumulation should be considered. The BAFs may be modified if changes can be justified by the data.

EPA identified the following concerns during application of the proposed methodology for defining BAFs:

—Six polynuclear aromatic hydrocarbons (3,4-benzofluoranthene, 11,12-benzofluoranthene, benzo[a]pyrene, 1,12-benzoperylene, 1,2:5,6-dibenzanthracene, indeno[1,2,3-cd]pyrene) are 5-ring PAHs. Field-measured BAFs for two 3-ring and two 4-ring PAHs ranged from 17 to 228, and it seems unlikely that the addition of another ring will increase the BAF to over 1000. The four measured BAFs that are available for PAHs are substantially lower than the BAFs that are predicted from Log P for those chemicals.

—Metabolism is likely to reduce both the BAF and food chain multiplier

enough to cause the BAF to be less than 1000 for two chemicals (4-chlorophenyl phenyl ether, dibutyl phthalate).

—The BCF for one chemical (phenol) was measured using radiolabeled chemical. Even though the parent chemical was verified, the resulting predicted BAF is so much higher than the BAF predicted from Log P that it is doubtful that the BAF for this chemical is above 1000.

—The BCF for one chemical (toluene) was measured using radiolabeled chemical. The parent chemical was not verified and the resulting predicted BAF is so much higher than the BAF predicted from Log P that it is doubtful that the BAF for this chemical is above 1000.

For these reasons, EPA is proposing to list the above ten chemicals as potential BCCs rather than BCCs. These ten pollutants are listed in part B of Table 6. The special regulatory provisions for BCCs in the proposed Guidance would not apply to these ten pollutants, although pursuant to section 510 of the Clean Water Act, the Great Lakes States or Tribes may also apply these provisions to any other pollutant, including the list of potential BCCs. The detailed derivation of the BAFs for all pollutants on Table 6 including the identified BCCs and potential BCCs is described in the technical support document, "Derivation of Proposed Human Health and Wildlife Bioaccumulation Factors for the Great Lakes Initiative," which is available in the administrative record.

The 28 pollutants with BAFs greater than 1000 for which EPA does not have the above concerns are listed in part A of Table 6. The special regulatory provisions for BCCs in the proposed Guidance would apply to these 28 BCCs, as well as to any other pollutant that the State or Tribe determines has a BAF greater than 1000, using the Methodology for Development of Bioaccumulation Factors in appendix B to part 132.

EPA invites comment on the choice of a BAF of 1000 at 5.0 percent lipids as the level which defines a BCC. The selection of a BAF of 1000 is a risk management decision that involves weighing information and policy considerations (rather than a risk assessment assumption that results from a scientific analysis). The Steering Committee made its recommendation on the basis of information available to them as managers of water quality programs. EPA is proposing this recommended cutoff of 1000 as an appropriate number to use for determining when there is a likelihood of relatively high exposure to humans and wildlife as a result of fish consumption. EPA recognizes that other numbers could be selected as a cutoff. During the deliberations of the Steering Committee, for example, alternative levels of 308 and 100 were suggested. A BAF of 308 represents the approximate value at which exposure from consumption of fish exceeds exposure from consumption of drinking water, under a human health criteria exposure assumptions of 6.5 gm/day of fish consumption and 2 L per day of drinking water consumption. Eight of the pollutants in Table 6 have proposed BAF values between 308 and 1000. Sixteen of the pollutants on Table 6 have proposed BAF values between 100 and 300. For reference purposes, a BAF of 1000 represents the point at which bioaccumulation due to dietary uptake in fish begins to be significant. Below this level, BAFs and BCFs are predicted to be nearly the same because virtually all bioaccumulation occurs as the result of pollutants from the water.

EPA invites comment on the proposed BAF level of 1000 and any alternative BAF levels for use in defending BCCs. EPA also invites comments on the lists of BCCs and potential BCCs, the methodology used to derive them, and all aspects of the issues related to BCCs. In particular, EPA invites comments on whether any or all of the potential BCCs should be listed as BCCs and any additional data relevant to these determinations.

The special regulatory provisions for BCCs in the proposed Guidance include portions of the antidegradation policy in appendix E, and procedure 3 (Total Maximum Daily Loads) and procedure 8 (WQBELs Below the Levels of Detection) in appendix F. The specific reasons for applying these provisions to BCCs are provided in sections I.D., VII, VIII.E, and VIII.H of this preamble. EPA invites comment on the manner in which these provisions are based, in part, on the definition of BCCs.

H. Adoption Procedures

Section 118(c)(2)(C) of the Clean Water Act requires the Great Lakes States to adopt water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System which are consistent with the final Guidance. If a Great Lakes State fails to adopt consistent provisions within two years of EPA's publication of the final Guidance, EPA is required to promulgate such provisions within the same two-year period.

Section 132.5 of the proposed Guidance specifies the procedures for State and Tribal submissions, and for EPA review and approval or disapproval of these submissions under part 132. Where possible, EPA has patterned the submission and approval process in proposed § 132.5 after the processes now in place for the water quality standards and NPDES programs, pursuant to sections 303 and 402 of the Clean Water Act, and believes the procedures in proposed § 132.5 satisfy the minimum procedural requirements of those programs. Therefore, EPA's review and approval of these submissions will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's NPDES program pursuant to section 402 of the Clean Water Act as provided in proposed § 132.5(f). In this way, one submission and approval procedure will satisfy all relevant statutory requirements and thereby maximize efficient use of State, Tribal, and EPA time and resources, and facilitate public participation.

Proposed § 132.5(a) requires the Great Lakes States and Tribes to adopt and submit for EPA review and approval the criteria, methodologies, policies and procedures developed pursuant to part 132 by a date no later than 18 months from the date of final publication of the part 132 requirements. Section II.B. of this preamble discusses the application of the requirements of section 118 to Indian Tribes. If an Indian Tribe has not received authorization to administer the NPDES program, EPA or a State authorized to do so will administer the requirements of part 132 on Indian lands and issue permits for discharges to the Great Lakes System consistent with this part. States, however, generally lack authority to administer NPDES programs on Indian lands, and no State within the Great Lakes basin is currently authorized to administer the program on Indian lands. See 40 CFR 123.1(h). EPA is proposing to establish this 18-month deadline for State and Tribal submissions in order to allow the full time available under the statute for EPA review and approval of submissions and for States and Tribes to correct any identified deficiencies, and still allow EPA to meet the section 118(c)(2)(C) requirement for review, approval or disapproval and promulgation by EPA, if necessary, within two years after the final publication of the Guidance.

Proposed § 132.5(b) identifies four elements that must be included in the

State and Tribal submissions: (1) The criteria, methodologies, policies, and procedures the State or Tribe has adopted pursuant to part 132; (2) a certification by the State or Tribal Attorney General or other appropriate legal authority of adequate legal authority to meet the requirements of part 132; (3) any other information required for submission of NPDES program modifications under 40 CFR 123.62; and (4) general information to aid EPA in determining whether the submitted criteria, methodologies, policies, and procedures are consistent with the Clean Water Act and part 132, plus information on general policies which may affect the application of the submitted criteria, methodologies, policies, and procedures, if any. This information must currently be included in any submissions for EPA approval of State revisions to water quality standards or proposed modifications to State NPDES programs under 40 CFR 131.6 and 123.62.

If a Great Lakes State or Tribe fails to submit criteria, methodologies, policies, and procedures to EPA for review, proposed § 132.5(c) provides that the requirements of this part will apply to discharges within the State or Federal Indian Reservation upon EPA's publication of the final Guidance in the **Federal Register** indicating the effective date of the part 132 requirements in the identified jurisdictions. EPA does not intend to provide at that time an opportunity for another round of public comment on the criteria, methodologies, policies, and procedures presented in the proposed Guidance. EPA believes that under these circumstances, today's public comment period will provide adequate notice and opportunity for comment on all issues related to the criteria, methodologies, policies, and procedures. Accordingly, EPA will issue the final Guidance identifying the criteria, methodologies, policies, and procedures that apply in the appropriate jurisdictions.

If a State or Tribe submits criteria, methodologies, policies, and procedures to EPA for review, EPA will issue a public notice and provide a 30-day period for public comment on all State or Tribal submissions under this part (proposed § 132.5(d)). This provision is included to conform with the existing public comment requirements for proposed modifications to State NPDES programs under 40 CFR 123.62(b). After consideration of public comments, EPA will either publish a notice of approval of the submission in the **Federal Register** within 60 days or notify the State or Tribe within 90 days that all or part of the submission is inconsistent with the requirements of the Clean Water Act or part 132 and identify changes necessary to obtain EPA approval. (Proposed § 132.5(d)(ii).) EPA will base the approval or disapproval of the part 132 submission on the requirements of the Clean Water Act and part 132. (Proposed § 132.5(e).)

If EPA approves all elements of the State or Tribal submission, the proposed Guidance would not require EPA to promulgate specific provisions for that State or Tribe in § 132.7. In contrast, if EPA instead notifies the State or Tribe that portions of the submission are inconsistent with the Clean Water Act or part 132, as discussed further above, and the State or Tribe fails to adopt the required changes within 90 days after the notification, EPA will publish a notice in the **Federal Register** identifying the approved and disapproved elements of the submission and a final rule in the **Federal Register** identifying the sections of part 132 which will apply in that jurisdiction. Under these circumstances, EPA will codify in § 132.6 the part 132 provisions which will apply in the Great Lakes States or Tribes that do not submit approvable regulations.

EPA is proposing this submission procedure in order to allow time for EPA review and approval if appropriate, State or Tribal notice and correction of any deficiencies identified during EPA review as necessary, and EPA publication of part 132 criteria, methodologies, policies, or procedures in whole or in part for the State or Tribe where required, within two years after the final publication of the Guidance as required by section 118(c)(2)(C). EPA believes there are two advantages to this approach. First, it gives States and Tribes the maximum amount of time EPA believes is possible under the statute to make their submissions.

Second, proposed § 132.5 simplifies the differing processes of promulgating standards, policies, and procedures by accounting for the minimum requirements for EPA approval or disapproval of water quality standards and NPDES program modifications under sections 303 and 402 of the Clean Water Act. EPA has patterned the proposed submission procedure after the well-established procedure for EPA approval or disapproval of State water quality standards under section 303(c) and 40 CFR part 131 and the procedure for submission of State NPDES program modifications under section 402 and 40 CFR 123.62. These procedures are familiar to EPA, States, Tribes, the regulated community and the public.

40 CFR 131.20 currently requires the State or Tribe to submit adopted water quality standards to EPA for review within 30 days of adoption. Section 303(c) provides that EPA must approve State water quality standards within 60 days of submission or disapprove the standards and identify needed changes within 90 days of submission. If the State standards are disapproved by EPA, the State has 90 days to adopt EPA's required changes. If such action is not taken, the Act requires EPA to promptly prepare necessary standards for the State. The State or Tribal water quality standard continues to be effective in the jurisdiction until EPA promulgates a new water quality standard. See also 40 CFR 131.21.

The current submission and review requirements for NPDES program revisions under section 402 are described in 40 CFR 123.62. All the Great Lakes States have approved NPDES programs; however, to date, EPA has not authorized any Great Lakes Indian Tribe to operate the NPDES program. The procedure for submission and review of NPDES program revisions is different in several respects from that of section 303(c), 40 CFR 131.20 and 131.21, and proposed § 132.5. For example, 40 CFR 123.62 does not provide a detailed timetable for review of proposed NPDES program revisions. Additionally, if a State or Tribe fails to submit materials pursuant to part 132 or EPA disapproves part of the submission, proposed §§ 132.5 (c) and (d) require application of those portions of part 132 to discharges within the State or Federal Indian Reservation.

Proposed § 132.5 of the proposed Guidance would provide that requirements of this part will become effective within a State or Federal Indian Reservation if the State or Tribe fails to make the necessary submission, or if one or more parts of the submission cannot be approved by EPA and the State or Tribe fails to correct the deficiency upon notice by EPA, following EPA's publication of the final Guidance in the **Federal Register** identifying the elements of the part 132 requirements that apply in the jurisdiction and their effective date in the jurisdiction. Because the requirements of part 132 proposed today will receive full public comment before the final part 132 Guidance is promulgated, EPA believes it is both unnecessary and an inefficient use of scarce resources to promulgate separate notices of proposed and final promulgation for each State or Tribe for which EPA must promulgate the part 132 requirements in whole or in part. By instead publishing a final notice of promulgation for each such State or Tribe, EPA will allow the State or Tribe

the maximum available time to submit the criteria to EPA and still give EPA sufficient time to publish part 132 criteria for the State or Tribe, if necessary, within the two-year statutory deadline.

Under the proposed Guidance, the submission and review procedures in § 132.5 will govern EPA review and approval of water quality standards and NPDES program revisions for Great Lakes States and Tribes under part 132 (§ 123.62(f)). EPA does not intend the provisions of proposed § 132.5 to change existing Clean Water Act rules governing the effectiveness of State or Tribal promulgated requirements. That is, consistent with the requirements of section 303(c), if a State or Tribe adopts a revised water quality criterion which is submitted to EPA for review and approval under proposed § 132.5, it is effective in the State or Tribe until EPA disapproves it and promulgates a new criterion. In contrast, State or Tribal adoption of NPDES regulations pursuant to proposed § 132.5 will not become recognized parts of the State or Tribal NPDES program until EPA approves the proposed modification. Of course, according to the proposed § 132.5 procedure, EPA must either approve a State or Tribal part 132 submission or disapprove and publish the final Guidance identifying the conforming part 132 requirements that must be applied to discharges in the Great Lakes System, for all part 132 criteria, policies, and procedures, including those which are NPDES program elements.

EPA also retains the ability to object to a proposed State or Tribal NPDES permit that is inconsistent with the Clean Water Act and NPDES regulations (40 CFR 123.44(c)(7)), or to withdraw a State or Tribal NPDES program that does not comply with the Clean Water Act and part 123 (40 CFR 123.63(a)). Once the requirements of this part become effective, they will provide an additional basis for EPA objection to the issuance of a proposed State or Tribal NPDES permit under § 122.44 or for withdrawal of NPDES program approval under § 123.63 if the provisions have not been adequately incorporated into individual permits or the NPDES program. To clarify this intention, EPA has also proposed conforming changes, which will apply only to Great Lakes States and Tribes, to the existing NPDES permitting regulations in 40 CFR 122.44(r); 123.25(a)(38); 123.44(c)(9); 123.62(f); and 123.63(a)(6). Similarly, EPA has proposed conforming changes to the existing water quality standards regulations in 40 CFR 131.1; 131.5 and 131.21(b) to reflect the submission and review procedures for adoption of water quality standards under part 132.

EPA invites comments on all aspects of proposed § 132.5, including comments on alternative procedures that would be efficient and effective and would satisfy the statutory requirements. Additionally, EPA specifically requests comment on whether the final Guidance should specifically distinguish between the NPDES program elements and water quality standards elements of part 132 or whether EPA should make this determination on a case-by-case basis for each part 132 submission. There are benefits to either approach. Identification of the NPDES program elements and water quality standards program elements in the final Guidance could facilitate uniform treatment of all part 132 submissions and provide certainty to EPA Regions, States, Tribes, the regulated community, and the public concerning the effectiveness of those elements during the EPA review process. On the other hand, flexibility in this matter is useful in EPA's experience because it is sometimes difficult to distinguish an NPDES program element from a water quality standards element due to differences in State adoption procedures and terminology. EPA requests comment on both approaches. Finally, EPA seeks comment upon whether any additional conforming changes should be made to the existing NPDES and water quality standards regulations to implement the requirements of proposed § 132.5.

I. Interpretation of "Consistent With"

Section 118(c)(2)(C) of the Clean Water Act requires the Great Lakes States and Tribes to adopt water quality standards, antidegradation policies, and implementation procedures for water within the Great Lakes System which are "consistent with" the final Guidance proposed today in part 132. Section 132.5(e) of the proposed Guidance specifies when EPA will determine that a State or Tribe submission is consistent with the requirements of part 132. Generally, the proposed Guidance provides that submitted criteria, methodologies, policies and procedures are consistent with part 132 if they are "equal to or more restrictive than" the provisions in the final Guidance.

EPA strongly encourages verbatim adoption of the final Guidance or adoption with only conforming changes, such as renumbering sections to conform with the State or Tribal regulations, or, for example, replacing "Great Lakes System" with "Lake Erie System." Adopting the Guidance verbatim would facilitate EPA approval and guarantee uniformity of these provisions throughout the Great Lakes System, especially with regard to the criteria methodologies. EPA recognizes, however, that some States or Tribes may desire to supplement or modify the final Guidance which EPA ultimately issues to incorporate program-specific concerns. Accordingly, in order to provide flexibility to State and Tribal regulatory agencies, proposed § 132.5 does not require verbatim adoption of all elements of the final Guidance as long as the State or Tribe can demonstrate that any such modification will not be less restrictive than the required provision in the final Guidance. Section 132.5(e)(3) clarifies EPA's intention to evaluate the State and Tribal submissions on a provision-by-provision basis by providing that if States or Tribes adopt provisions more restrictive than the final Guidance, the more restrictive provision may not be offset by relaxation of other specific elements of the final Guidance. EPA believes that this condition is appropriate to ensure a minimum level of consistency in implementation of these requirements throughout the Great Lakes System. EPA requests comments, however, on this approach, including whether and, if so, under what circumstances the final Guidance should instead allow relaxation of any particular provisions to offset other more stringent provisions adopted in State or Tribal programs.

EPA recognizes that not requiring verbatim adoption of the final criteria methodologies, implementation procedures, and antidegradation policies will require case-by-case determinations of the adequacy of a State or Tribal submission, with the possibility of minor inconsistencies developing between approved programs in the Great Lakes System. Because of the length and complexity of the Guidance, however, EPA also recognizes that changes beyond conforming changes may be necessary to enable State and Tribal programs to function appropriately. EPA believes that the proposed approach balances the competing interests by providing some flexibility to the Great Lakes States and Tribes while still ensuring adoption of programs that satisfy all minimum requirements of the final Guidance. EPA invites comments on all aspects of this approach and any other alternative approaches, including whether the final Guidance should require verbatim adoption of all elements.

In §§ 132.5(e)(1) and 132.5(e)(2) EPA is proposing specific provisions concerning how EPA will determine that State or Tribal numeric criteria and

interpretation of narrative criteria are consistent with the final Guidance. The provisions operate differently depending on which pollutants are involved, and whether the State or Tribe has adopted numeric criteria for the pollutant.

For pollutants listed in Tables 1, 2, 3 and 4, EPA will determine that the submission is consistent with part 132 if the Great Lakes State or Tribe has adopted criteria corresponding to each of the criteria listed in Tables 1 through 4, and the State or Tribal criteria are equal to or more restrictive than each of the criteria in the Tables. If the State or Tribe has applied site-specific criteria modifications, they will need to demonstrate that the site-specific criteria modification procedures of appendix F were used, or if other procedures were used, such other procedures produce site-specific criteria equal to or more restrictive than criteria developed through application of appendix F procedures.

For pollutants other than those listed in Tables 1, 2, 3 and 4, the requirements of § 132.5(e)(2) are intended to ensure that State or Tribal criteria methodologies and narrative implementation procedures result in criteria or values equal to or more restrictive than the proposed Guidance methodology produces.

—If the Great Lakes State or Tribe has adopted numeric criteria for the pollutant in its water quality standards, then the State or Tribe must demonstrate that it either used the appropriate methodology specified in the final Guidance, or, using a different methodology, obtained criteria equal to or more restrictive than the Guidance's methodology would produce. If the numeric criteria were adopted into State or Tribal water quality standards prior to the date of final publication of this part, § 132.5(e)(2)(ii) provides that the Great Lakes State or Tribe may alternatively choose to demonstrate to EPA that it has adopted a procedure by which the State or Tribe will use Guidance-based criteria and values, instead of the numeric criteria adopted in its standards, when it develops water quality-based effluent limits and total maximum daily loads if the Guidance-based criteria and values are more restrictive than the adopted criteria. The reason for including this alternative demonstration is to give States or Tribes the administrative flexibility to determine the adequacy of such criteria at a later date—that is, the time when water quality-based effluent limits or total maximum daily loads are developed—rather than the time of the submission required by § 132.5. This may be a reasonable alternative for States that have adopted a large number of numeric criteria into their water quality standards and are unable to review all criteria for consistency with this part in time for the submission required by § 132.5. To implement such an alternative procedure, the State will need to demonstrate that it has in place the regulatory mechanisms to ensure that the State will apply the methodologies in the final Guidance to develop water quality-based effluent limits and total maximum daily loads if existing State numeric water quality criteria would result in less restrictive effluent limitations.

—If the Great Lakes State or Tribe has not adopted numeric criteria for the pollutant in its water quality standards, then the State or Tribe must demonstrate that it has adopted a procedure by which water quality-based effluent limits and total maximum daily loads will be developed using water quality criteria and values derived pursuant to the Guidance Tier I and Tier II methodologies required by § 132.4(c).

EPA believes that the requirements of § 132.5(e) are appropriate to ensure a minimum level of consistency in implementation of the Guidance throughout the Great Lakes System in accordance with the legislative intent of the Great Lakes Critical Programs Act (see section II.E of this preamble). EPA invites comment on all aspects of these requirements.

J. Precedential Effect of Elements of the Guidance

The requirements in the proposed Guidance are expressly applicable only to the waters of the Great Lakes System. However, the proposed Guidance addresses many central elements of existing National and State water quality programs. For example, all States currently have regulations and/or guidance addressing methodologies to derive and implement water quality criteria and antidegradation policies, and procedures for determining TMDLs for specific water bodies. Although some elements of the proposed Guidance incorporate data or considerations specific to the Great Lakes System, EPA believes that many portions might be beneficially applied in other jurisdictions.

EPA is not proposing nationwide application of any portions of the proposed Guidance because section 118(c)(2) of the Clean Water Act is limited to promulgation of Guidance for the Great Lakes System. EPA does request comment, however, on whether EPA should issue National guidance or propose any modifications to 40 CFR parts 122–124, 130 and 131 in the future to correspond with specific elements of today's proposed rule.

K: Endangered Species Act

Section 7(a)(2) of the Endangered Species Act (ESA) requires each Federal agency, in consultation with the U.S. Fish and Wildlife Service (FWS), or the National Marine Fisheries Service for species under its jurisdiction, to ensure that actions authorized, funded or carried out by the Federal agency are not likely to jeopardize the continued existence of any endangered or threatened species listed under the ESA, or result in the destruction or adverse modification of such species' critical habitat (i.e., are not likely to "cause jeopardy"). EPA has initiated informal consultation with the FWS to insure that implementation of part 132 by EPA, States and Tribes is not likely to cause jeopardy for species in the Great Lakes System. While EPA has not determined that consultation is required for all aspects of the proposed Guidance at this stage, consultation on the proposed Guidance will help insure that submissions by the Great Lakes States and Tribes under part 132 will provide for adequate protection of endangered and threatened species, and thereby help avoid delays in EPA's approval of such submissions. EPA will consider the results of our consultation with the FWS, along with all public comments on today's proposal, in determining appropriate requirements for endangered or threatened species in the final Guidance.

As a result of the consultation, EPA may determine that provisions should be included in the final Guidance specifically targeted to ensuring the protection of endangered or threatened species. For example, one approach would be to require in § 132.5 of the proposed Guidance that any submission by a Great Lakes State or Tribe include provisions to ensure that the development and implementation of criteria, methodologies, policies and procedures under part 132 are not likely to cause jeopardy. Such a provision in the final Guidance would authorize EPA to disapprove a submission by a State or a Tribe that did not ensure that jeopardy of endangered or threatened species would be avoided, or to require a State or Tribe to include measures or alternatives recommended by the FWS to reduce impacts to endangered and threatened species.

In addition, EPA could adopt in the final Guidance specific text that States and Tribes would need to include in their submissions in order to ensure adequate protection of endangered and threatened species. Regarding implementation procedures, the Guidance could, for example, require that States and Tribes include provisions stating that mixing zones and variances will not be permitted to the extent they will likely cause jeopardy of endangered and threatened species. Similarly, the final Guidance could require that antidegradation policies submitted for EPA approval include a requirement that water quality be maintained at a level necessary to insure that endangered or threatened species are not likely to be jeopardized due to water quality conditions. EPA solicits suggestions of text that EPA could include in the final Guidance to ensure that implementation procedures and other relevant aspects of the proposed Guidance will provide for protection of endangered and threatened species.

With regard to water quality criteria, EPA expects to consult on the aquatic life and wildlife water quality criteria and methodologies in the proposed Guidance. To the extent these criteria and methodologies are determined in this consultation to be protective of endangered and threatened species in the Great Lakes System, adoption of these provisions by States and Tribes would be approvable by EPA. If these criteria and methodologies are determined not to be protective of certain species in the Great Lakes System, EPA is considering including text requiring that States and Tribes adopt adequately protective site-specific criteria. If a State or Tribe adopts site-specific modifications to aquatic life criteria under section A.1.a of procedure 1 of appendix F to part 132, the State or Tribe will need to ensure that those modifications will provide adequate protection of endangered or threatened species. In addition, EPA is considering the option of requiring States and Tribes to modify aquatic life and wildlife criteria/values on a site-specific basis to provide protection appropriate for endangered and threatened species, and EPA solicits public comments on such an approach.

By consulting with the FWS under section 7 of the ESA on the proposed Guidance, EPA is seeking to carry out its responsibilities under the CWA in a manner that also helps achieve the objectives of the ESA. Obviously, the two statutes promote similar goals, because improving water quality can have beneficial effects on the viability of endangered or threatened aquatic life and wildlife. EPA believes that EPA, States and Tribes should pay particular attention to preventing water quality degradation where it would have detrimental effects on endangered and threatened species. If EPA were to include provisions addressing endangered and threatened species in the Guidance, however, EPA would not be seeking to impose any procedural obligation on Great Lakes States and Tribes to consult with the FWS under section 7(a)(2) of the ESA. The section 7 consultation provisions apply only to Federal agencies (although Federal agencies can in certain cases designate non-Federal representatives for purposes of informal consultation). Rather, EPA would be explicitly addressing the need for protecting endangered and threatened species in order to ensure that promulgation of the Guidance and approvals of submissions by Great Lakes States and Tribes are consistent with the no jeopardy standard in section 7(a)(2) of the ESA.

L. Request for Comments

EPA has received and placed in the public docket materials submitted during the public proceedings on the Great Lakes Water Quality Initiative. EPA considered these comments in the development of the proposed Guidance. Because these materials contain comments on draft provisions that have been superseded by the proposed Guidance and EPA would have difficulty identifying portions that remain relevant to this proposal, EPA will not consider them in the development of the final Guidance. Additionally, EPA believes that the time available for promulgation of the final Guidance can be used most efficiently and effectively by addressing those issues that have not already come before EPA. Accordingly, EPA advises the public that for the purposes of exhaustion of administrative remedies, new comments must be submitted based on the proposed Guidance.

EPA requests comment on each element of the proposed Guidance, including all subjects and issues raised in the preamble discussion whether or not specific regulatory text has been provided in the proposed Guidance, and any suggested alternative requirements or combinations of requirements to address these elements and issues in the final Guidance. EPA may promulgate final rules based on any of the issues or subjects discussed in the proposed Guidance or based on combination of possible requirements to address these subjects and issues. EPA expects to finalize requirements in the final Guidance addressing these subjects and issues based upon the discussion in the preamble and evaluation of all submitted comments. EPA will not make any final decisions on any element or issue of the final Guidance until after full consideration of the public comments.

III. Aquatic Life

A. Introduction and Purpose

EPA has broad authority to develop criteria to protect aquatic life in Great Lakes waters. Section 304(a)(1) of the Clean Water Act generally authorizes EPA to develop criteria to protect aquatic life in all waters of the United States. Section 118(c)(2)(A) of the Clean Water Act requires EPA to develop specific numeric criteria to protect aquatic life in the Great Lakes. This requirement implements portions of the Great Lakes Water Quality Agreement of 1978 (Agreement). One of the Agreement's "General Objectives" is freeing the Great Lakes System from substances resulting from human activity that will adversely affect aquatic life. Several of the "Specific Objectives" for individual pollutants set out in Annex 1 of the Agreement are also specifically directed at the protection of aquatic life. Moreover, both the legislative history to section 118(c) and the text of the Agreement emphasize the goal of more consistent water quality criteria across the Great Lakes.

Observed effects on aquatic life, such as population declines and abnormal reproduction, provide clear evidence that the goals of the Clean Water Act and the objectives of the Great Lakes Water Quality Agreement for aquatic life are not being met throughout the Great Lakes System (Sixth Biennial Report on Great Lakes Water Quality, April, 1992). This report is available in the administrative record for this rulemaking. To improve water quality and to promote more consistent protection of aquatic life within the Great Lakes System, EPA is proposing a new approach to developing aquatic life criteria for the Great Lakes. Some of the criteria in the proposed Guidance are more restrictive than the nationally applicable criteria EPA has published under Clean Water Act section 304(a). Further, EPA is proposing to promote consistency by requiring Great Lakes States and Tribes to adopt specific criteria at least as stringent as those proposed herein and specific methodologies identical to or more stringent than those proposed herein. As explained in more detail below, EPA believes that the proposed criteria for aquatic life and the requirements for implementing them will conform with

the objectives of the Great Lakes Water Quality Agreement and be "no less restrictive" than National water quality criteria and guidance.

As described below, EPA is proposing Great Lakes Water Quality Guidance for Aquatic Life which contains two tiers, subsequently referred to as Tiers I and II. This tiered approach allows Great Lakes States and Tribes to provide more consistent protection of aquatic life from the discharge of pollutants, even if information on the pollutant's effects is too limited to meet the strict data requirements in the proposed Guidance for setting aquatic life criteria under Tier I.

The Aquatic Life Tier I methodology is similar to "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (Stephan, et al., 1985), which is the current National guidance for developing aquatic life criteria. A copy of the 1985 National Guidelines is available in the administrative record for this rulemaking. Copies are also available upon written request to the person listed in section XIII of this preamble. The 1985 National Guidelines can also be obtained through the National Technical Information Service (PB 85–227049). The Tier I methodology is to be used in deriving Great Lakes Aquatic Life Criteria for use in State and Tribal Water Quality Standards. The Tier I criteria are based on the latest scientific knowledge and are derived using an extensive aquatic toxicological database.

The Aquatic Life Tier II methodology is "a new tool" for regulating discharges within the Great Lakes System when sufficient data do not exist to derive a Tier I criterion. While similar concepts have been employed by individual States within the Great Lakes System, this Tier II methodology will provide a consistent approach for all Great Lakes States and Tribes. This methodology utilizes limited toxicological data to derive conservative regulatory values for individual pollutants. The Tier II methodology will be used in conjunction with the proposed whole effluent toxicity requirements, in interpreting the State's narrative criteria (e.g., no toxic pollutants shall exist in toxic amounts). Tier II values can serve as the basis for some regulatory decisions, such as permit limitations. Although the State or Tribe will have authority to adopt Tier II values as standards, it is not intended that Tier II values will normally be adopted as State water quality standards. Rather, EPA believes it is more desirable for the regulatory agencies and/or dischargers to continue to supplement data on pollutants to the point where a Tier I criterion can be calculated and subsequently adopted as a criterion for use in State and Tribal water quality standards.

B. Tier I Criteria

1. Methodology

The Committees of the Initiative chose, as the starting point for the development of the Aquatic Life Tier I methodology, EPA's "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985 National Guidelines) as cited in 50 FR 30784 (July 29, 1985) and developed under section 304(a) of the Clean Water Act.

The 1985 National Guidelines contain provisions for deriving both freshwater and saltwater criteria. As the Great Lakes System is composed entirely of fresh water, those portions of the 1985 National Guidelines which pertain to fresh water serve as the basis for the Tier I aquatic life methodology in the proposed Great Lakes Water Quality Guidance. Since the Great Lakes Tier I methodology closely resembles the 1985 National Guidelines, the following narrative is a discussion of the 1985 National Guidelines and the specific changes made to it in the proposed Guidance for Tier I aquatic life methodology.

The proposed Great Lakes Guidance, like the 1985 National Guidelines, results in the derivation of two criteria concentrations to protect aquatic life for any given pollutant. The first of these, the Criterion Maximum Concentration (CMC), is designed to protect aquatic life from effects of short term or acute exposures. The second, the Criterion Continuous Concentration (CCC), is designed to protect against effects to aquatic life due to long term or chronic exposure. In order to derive a CMC for a pollutant, it is necessary that acceptable acute toxicity studies exist for aquatic animal species in at least eight families which represent differing habitats and taxonomic groups. These eight families are intended to represent a wide spectrum of aquatic animals. The Great Lakes aquatic life methodologies provide guidance on determining data acceptability.

Results of acute toxicity studies are expressed in terms of EC50s or LC50s. An EC50 is the concentration which will cause an adverse effect to 50 percent of the exposed individuals (e.g. immobility, possibly including death) within a given period of time (typically 48 hours for daphnids and other cladocerans, and 96 hours for other aquatic animals). An LC50 is the concentration of a pollutant which will cause the death of 50 percent of the exposed individuals within these same time frames. EPA is proposing to follow the approach established in the 1985 National Guidelines for deriving a Final Acute Value (FAV) to protect a broad range of aquatic species by ranking the Genus Mean Acute Values (geometric means of the Species Mean Acute Values for each genus), and then interpolating or extrapolating to estimate the acute value for 95 percent of the genera tested. As described in the 1985 National Guidelines, the FAV must be set equal to the lower of the 95th percentile value, or the Species Mean Acute Value for a species of commercial or recreational importance (the Tier I methodology differs from the 1985 National Guidelines by specifying that the FAV should only be lowered for a species that is recreationally or commercially important to the Great Lakes System). The CMC is equal to one-half the FAV. The FAV is divided by two to convert a concentration toxic to 50 percent of the individuals of the tested species, to a concentration not acutely toxic for nearly all individuals of the species.

EPA believes that the proposed methodology provides a broad base of protection for the aquatic life of the entire Great Lakes System. There are documents for the sixteen proposed Tier I criteria, within the Administrative Record, which contain detailed information on the range of species tested.

The Technical Work Group considered inserting a provision in the Great Lakes Tier I procedure that would also allow the lowering of the FAV to protect "ecologically important" species of the Great Lakes. However, it was felt that it would be unnecessary given the scope and protective nature of the proposed Guidance to single out particular species for additional protection on the basis of "ecological importance", because the method generally provides protection for the entire ecosystem. Furthermore, the Technical Work Group could not reach consensus on identifying any individual species as "ecologically important" or defining the term "ecologically important". Therefore, the proposed Guidance does not include provisions for lowering an FAV for "ecologically important" species. This is consistent with the 1985 National Guidelines. EPA invites comment on this issue, and particularly on the issues of how to define "ecologically important" species for the Great Lakes, and whether or not such "ecologically important" species

are adequately protected by the proposed guidance.

EPA is proposing slightly greater modifications to the 1985 National Guidelines' approach to chronic exposures. In the 1985 National Guidelines, the CCC is the lowest of the Final Chronic Value (FCV), the Final Plant Value (FPV) or the Final Residue Value (FRV). The reason the 1985 National Guidelines set the CCC as the lowest of the FCV, FPV, or the FRV is to provide protection for aquatic plants, wildlife and the marketability of commercially important aquatic species, as well as other aquatic animals. As explained in more detail below, EPA is proposing to retain the options of using either a FCV or a FPV to determine the CCC, but proposing to delete the option of using FRVs.

EPA is proposing to follow the approach established in the 1985 National Guidelines by allowing the FCV to be calculated in one of two ways. If acceptable chronic toxicity studies (i.e., studies which span a significant portion of the life cycle of the tested species and which measure endpoints such as growth and reproduction) exist for the required eight families of aquatic animals (which represent differing habitats and taxonomic groups), then the FCV can be calculated using the same mathematical procedure as was used in the derivation of the FAV. If acceptable chronic toxicity studies do not exist for the eight families, the FCV must be set equal to the lower of the quotient of the FAV divided by the Final Acute-Chronic Ratio (ACR). The Acute-Chronic Ratio (ACR) is a way of relating acute and chronic toxicities. To derive an ACR, comparable acute and chronic toxicity studies have been conducted under similar conditions for a given species. From comparable measurements of acute and chronic values, an ACR is calculated by dividing the measured acute value by the measured chronic value. EPA is proposing to follow the 1985 National Guidelines by requiring ACRs for at least three families of aquatic animals. The Final Acute-Chronic Ratio (FACR) must be either the geometric mean of some or all of the species ACRs or another value appropriate for sensitive species.

The 1985 National Guidelines allow the use of ACRs for saltwater species in the derivation of the FCV for freshwater animals. Because the Great Lakes are freshwater lakes, the proposed Great Lakes Guidance, while still allowing for the use of saltwater ACRs, expresses a preference for the use of freshwater ACRs. EPA invites comment on the preference for freshwater acute-chronic ratios in calculating a Final Chronic Value to protect species within the Great Lakes System.

As with the FAV, the Great Lakes Guidance provides for the lowering of the FCV, where necessary, to protect a commercially or recreationally important species within the Great Lakes System. However, similar to the earlier discussion pertaining to FAVs, the Guidance does not include an option of lowering the FCV for "ecologically important" species. EPA invites comment on this issue.

A plant value is the result of a 96-hour test conducted with an alga, or a chronic test conducted with an aquatic vascular plant. The FPV is obtained by selecting the lowest result from a test with an important aquatic plant species, in which the endpoint was biologically important (e.g., survival) and the test concentrations were measured. EPA is proposing to retain the provision of setting the CCC equal to the lower of the FCV or the FPV, as in the 1985 National Guidelines.

The 1985 National Guidelines indicate that the FRV is intended to prevent concentrations of pollutants in commercial or recreational aquatic species from affecting the marketability of those species or affecting wildlife that consume aquatic life. By preventing the exceedance of applicable FDA action levels (concentrations of pollutants set by FDA as acceptable amounts in marketable fish tissues for human consumption), marketability of those species can be maintained. The FRV is also intended to protect wildlife, including mammals and birds, that consume aquatic organisms.

The proposed Great Lakes Guidance does not include provisions for calculating a FCV on the basis of a FRV, as specified in the 1985 National Guidelines. (This change, in part, results in criteria which are different from published National aquatic life criteria which are based on a FRV, e.g., dieldrin, endrin, and mercury.) There are several reasons for this change.

First, a separate methodology for deriving criteria for the protection of wildlife is being proposed under a separate portion of the Guidance, whereas no such guidance currently exists on the National level. The FRV is currently utilized to provide protection to wildlife within the 1985 National Guidelines for the protection of aquatic life. EPA believes that the wildlife criteria proposed in the proposed Guidance will be derived in a manner that would yield more appropriate criteria to protect wildlife than the FRV. More detailed information on the wildlife criteria in the proposed Guidance may be found in section VI below. Thus, for the purposes of the Great Lakes System, provision for a CCC based on impacts to wildlife would be duplicative and less Great Lakes-specific. EPA invites comment on this issue, and particularly on whether it is necessary to have provisions, within the aquatic life guidance, to ensure protection of wildlife, rather than having a separate methodology directed at protection of wildlife.

Further, EPA believes that the assumptions which are made in the development of an FDA action level, and particularly the fact that those action levels are based upon National fish consumption values, makes the application of these action levels inappropriate for use in the proposed Guidance. Rather, EPA believes that the derivation of criteria for the protection of human health within the Great Lakes System more appropriately takes this consideration into account with Great Lakes fish consumption values. Therefore, EPA believes that the human health methodologies being proposed elsewhere in this notice will provide an appropriate level of protection to humans consuming Great Lakes fish.

More detailed information on the human health criteria proposed may be found in section V below. Again, given the human health criteria proposal, EPA believes that for the purposes of the Great Lakes, provision for usage of FDA action levels would be duplicative and less Great Lakes-specific. Thus, the proposed Guidance only provides for the derivation of a CCC based either on a FCV or a FPV. EPA invites comment on this issue, and particularly on the issue of deleting the use of a FRV.

In its December 16, 1992, report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," the EPA's Science Advisory Board (SAB) recommended that EPA consider both the biologically active form and the total contaminant concentrations of a pollutant when establishing water quality criteria. This report is available in the administrative record for this rulemaking. Within the Tier I methodology, section I.A.3 of appendix A to part 132, the State or Tribe is given guidance in determining for what form of the pollutant to derive the criterion. The State or Tribe is given guidance in determining an operational analytical component to the criterion that describes the analytical method that is intended. The methodology itself does not specify a particular analytical method that must be used. The analytical method chosen must accurately reflect the form of pollutant for which the criterion is derived. The

criteria documents for 9 of the 16 pollutants for which Tier I criteria are being proposed in the proposed Guidance identify an analytical methodology that should be used. The State or Tribe has the flexibility to choose the most appropriate analytical method. The State could choose, for example, to derive a criterion for the bioavailable form, or for the total contaminant concentration. Although criteria developed using the Tier I method in the proposed Guidance may not consider both the biologically active and total contaminant concentration, a mechanism within the site-specific criteria modification procedure, procedure 1 of appendix F to part 132 may be used to address this concern. Because the bioavailability of a pollutant is linked to the water chemistry within a specific receiving water or effluent, EPA believes the water-effect ratio approach, as described in the 1983 Standards Handbook, Chapter 4 and as modified by the 1992 Interim Guidance on Interpretation and Implementation of Aquatic Life Criteria for Metals, which is available in the administrative record of this rulemaking, is the appropriate mechanism to address bioavailable versus total concentrations of contaminants. The water-effect ratio approach is a biological method which compares bioavailability and toxicity of a contaminant in receiving waters versus laboratory test waters. EPA invites comment on whether bioavailability of contaminants is adequately addressed using site-specific modification approaches, as well as alternatives to address the issue of expressing toxicity of both bioavailable and total contaminant concentrations.

The 1985 "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985 National Guidelines) have previously undergone scientific peer review and public review and comment, and have been revised as appropriate. Therefore, for those portions of the Tier I aquatic life methodology that are the same as the 1985 National Guidelines, EPA does not intend to address the issues already addressed by EPA in response to previous comments in this proposed rulemaking.

2. Selection of Pollutants for Application of Tier I Criteria Methodology

The Great Lakes Water Quality Guidance specifies a number of numeric limits on pollutants in ambient Great Lakes waters to protect aquatic life, along with the methodology used in calculating criteria. To begin the process of developing criteria and to evaluate the proposed methodologies, the Initiative Committees selected 26 pollutants for which there are current National water quality criteria for the protection of aquatic life and which are included in Table 6 to derive Tier I aquatic life criteria (see list of 26 pollutants in the Administrative Record). Of these 26 pollutants, EPA is proposing, in the proposed Guidance, numeric (Tier I) criteria for 16. EPA is proposing numeric criteria derived using the proposed Tier I Aquatic Life methodology for an additional pollutant for which there is currently not a National criterion (phenol). EPA has derived draft National criteria for phenol, which are currently undergoing EPA review and will be proposed in the **Federal Register** as draft National Clean Water Act section 304(a) criteria, once that review is complete.

The reasons EPA is not proposing Tier I criteria for the other nine pollutants are set forth below. First, some of the National aquatic life criteria were developed before 1985, under a methodology different from the 1985 National Guidelines. The earlier methodology did not have the same minimum data requirements as the current Tier I methodology or the 1985 National Guidelines. The data used to determine the 1980 criteria for aldrin, chlordane, DDT, endosulfan, heptachlor, lindane, and PCBs, while adequate under the earlier methodology, do not meet the minimum data requirements established in the 1985 National Guidelines. (Data were not sufficient to calculate a chronic Tier I criterion for lindane; however, there was a sufficient data set to calculate an acute Tier I criterion.) Therefore, these pollutants do not meet the minimum data requirements needed to derive Tier I aquatic life criteria even though there are existing National criteria for them.

Further, there are three pollutants that were developed under the 1985 National Guidelines for which the Agency made exceptions to its minimum data requirements. The National aquatic life criteria for lead ("Ambient Water Quality Criteria for Lead—1984"), toxaphene ("Ambient Water Quality Criteria for Toxaphene—1986") and chlorpyrifos ("Ambient Water Quality Criteria for Chlorpyrifos—1986") have data for only seven of the eight families required. EPA believes that the National criteria for these pollutants would not be significantly different with the addition of the eighth data point. However, the Initiative Committees proposed to follow the Tier I methodology, as written. In addition, the Tier II methodology allows for the missing data to be provided or developed by the regulatory agency or permittee. Therefore, Tier I aquatic life criteria were not calculated for lead, toxaphene, and chlorpyrifos. The Steering Committee believed that the Tier II methodology should be used for all pollutants of initial focus in the Great Lakes Water Quality Initiative (i.e., pollutants in Table 6) which do not meet the data requirements in the Tier I methodology. EPA notes that it continues to believe that the decision to allow exceptions to the database requirements for these three pollutants was reasonable for the National criteria, since EPA has not developed any procedure resembling Tier II that could be used as a "fallback" on the National level.

EPA is proposing to follow the Steering Committee's proposals not to promulgate, at this time, specific numeric criteria for these nine pollutants. EPA requests comment on the alternative proposal of requiring States and Tribes to adopt the current National criteria for these pollutants, even though these National criteria are based on methods developed before 1985 or on less than the minimum data requirements for the 1985 method. The fact that criteria for these specific pollutants are not being proposed in the proposed Guidance does not mean that criteria cannot, or will not, be developed in the future. Moreover, the States and Tribes will be able to regulate these pollutants using the proposed Tier II methodology before any criteria are developed.

Aquatic data exists to derive aquatic life criteria for aluminum. However, due to time and resource limitations, aquatic life criteria for aluminum could not be derived. As proposed, this Guidance would leave the derivation of aquatic life criteria for aluminum to the States. EPA requests comment on this approach and alternatively whether EPA itself should derive aquatic life criteria for aluminum.

3. Tier I Numeric Criteria

Table III–1 presents CMCs, or acute criteria, calculated using the proposed Tier I methodology for aquatic life. For comparison, the CMCs of existing National criteria are also included. Differences between National and Great Lakes Tier I acute and chronic criteria can be attributed to one or more of three reasons.

TABLE III–1.—ACUTE AMBIENT WATER QUALITY CRITERIA FOR AQUATIC LIFE

Chemical	Great Lakes CMC[a]	National CMC[a]
Arsenic (III)	340	360
Cadmium[b]	2.1	1.8
Chromium (III)[b]	1000	980
Chromium (VI)	16	16
Copper[b]	7.3	9.2
Cyanide, free	22	22
Dieldrin	0.24	[d]2.5
Endrin	0.09	[d]0.18
Lindane	0.95	[d]2.0
Mercury (II)	0.83	2.4
Nickel[b]	260	790
Parathion	.065	.065
Pentachlorophenol[c]	5.3	5.5
Phenol	3700	.....
Total Selenium	20	20
Zinc[b]	67	65

[a] All values are in µg/L .
[b] The toxicity of this chemical is hardness related; the criterion expressed is at a hardness of 50 mg/L.
[c] The criterion for this chemical is pH dependent; the criterion expressed is at a pH of 6.5.
[d] This value is an FAV that was calculated according to the 1980 guidelines. Although the CMC = FAV/2 in the 1985 National Guidelines, there is no CMC in the 1980 guidelines and the procedure used to derive the FAV is different from that used in the 1985 National Guidelines.

First, the existing National criteria were derived between 1980 and 1987. Some of the criteria derived using the Great Lakes Guidance were calculated using data published subsequent to individual National criteria documents. Those chemicals for which this applies are: cadmium, chromium, copper, dieldrin, endrin, lindane, mercury, nickel, selenium, silver, and zinc. The development of an updated database resulted in less restrictive acute and/or chronic criteria for cadmium, chromium III, and zinc as compared to National criteria. However, EPA believes that the differences between the proposed Great Lakes criteria and the National criteria are insignificant. Furthermore, it is EPA's position that usage of the Great Lakes criteria is more appropriate than the National criteria because they are based on more recent data. EPA, however, requests comment on the option of promulgating the National criteria values for those pollutants which have more stringent National criteria values.

Secondly, as mentioned earlier, some of the National criteria were derived using a methodology which preceded the 1985 National Guidelines. Where sufficient data existed, the committees recalculated the criteria, to be consistent with the methodology being proposed. Those chemicals for which this applies are: Dieldrin, endrin, and hexachlorocyclohexane (lindane) (chronic criteria only). None of these proposed criteria, however, are less restrictive than the current National criteria.

Third, some corrections were required in some of the National criteria documents. Some of the data used in deriving the National criteria were deleted because they were not considered acceptable under the current toxicity testing protocol described in sections II, III, IV, V, VI, and VII of the proposed Great Lakes methodology for Tier I aquatic life criteria (appendix A to part 132). The pollutants for which this applies are copper, dieldrin and endrin. None of these changes produced criteria that are less restrictive than the National criteria.

A technical support document, "Great Lakes Water Quality Initiative Water Quality Criteria for Protection of Aquatic Life in Ambient Water, Criteria Documents," discusses the derivation of each of the Tier I acute criteria and the toxicity studies from which the criteria were derived are available in the administrative record for this rulemaking. The proposed Guidance would require that the numeric criteria in Table 1 to part 132 be adopted by the Great Lakes States and Tribes and incorporated into their ambient water quality standards. The specific requirements on how these criteria are to be incorporated into State and Tribal water quality standards are discussed in section II of this preamble.

Table III–2 presents CCCs, or chronic criteria, calculated using the proposed Tier I methodology for aquatic life. For comparison, the CCCs of existing National criteria are also included. In addition to the reasons cited earlier concerning differences between National and Great Lakes CMCs, several of the Great Lakes CCCs are affected by the preference of using freshwater ACRs.

TABLE III–2.—CHRONIC AMBIENT WATER QUALITY CRITERIA FOR AQUATIC LIFE

Chemical	Great Lakes CCC[a]	National CCC[a]
Arsenic (III)	150	190
Cadmium[b]	0.78	0.66
Chromium (III)[b]	49	120
Chromium (VI)	11	11
Copper[b]	5.2	6.5
Cyanide, free	5.2	5.2
Dieldrin	0.056	[d]0.0019
Endrin	0.037	[d]0.0023
Mercury (II)	0.44	[d]0.012
Nickel[b]	29	88
Parathion	0.013	0.013
Pentachlorophenol[c]	3.3	3.5
Phenol	120	.....
Total Selenium	5.0	5.0
Zinc[b]	80	59

[a] All values in µg/L.
[b] The toxicity of this chemical is hardness related; the criterion expressed is at a hardness of 50 mg/L.
[c] The toxicity of this chemical is pH related; the criterion expressed is at a pH of 6.5.
[d] Based upon Final Residue Value.

The derivation of each of these chronic criteria, and the toxicity studies upon which they are based, are also discussed in "Great Lakes Water Quality Initiative Water Quality Criteria for Protection of Aquatic Life in Ambient Water, Criteria Documents." This document is available in the administrative record for this rulemaking. The proposed Guidance would require that the numeric criteria in Table 2 to part 132 be adopted by the Great Lakes States and Tribes and incorporated into their ambient water quality standards. The specific requirements on how these criteria are to be incorporated into State and Tribal water quality standards are discussed in section II of this preamble.

4. Potential Changes to National Guidelines

EPA periodically reviews and updates the methodology which is used to derive National aquatic life criteria to accurately reflect the latest scientific knowledge. Currently, an EPA work group is reviewing "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985 National Guidelines). EPA may propose changes to the 1985 National Guidelines in 1993. Within the 1993 proposal, EPA may choose to incorporate some or all of those changes into the Great Lakes Tier I methodology, as described in the proposed Guidance. EPA advises all persons with an interest in the Tier I criteria to watch for the proposal on revisions to the 1985 National Guidelines.

C. Tier II Values

The Initiative Committees struggled with how to regulate pollutants for which an extensive data base, as required for the Tier I methodology and the 1985 National Guidelines, does not exist. In many cases, States and Tribes

need to regulate discharges for which a full complement of aquatic toxicity data is not available for a particular pollutant. Some of the Great Lakes States and Tribes, such as Ohio and Michigan, currently have procedures that are intended for use as translator mechanisms for narrative criteria (e.g., no toxic substances in toxic amounts). The Steering Committee wanted to ensure consistency among States and Tribes in using limited data to derive values for regulating discharges in the Great Lakes System. The Steering Committee also wanted to develop a methodology to be used as a translator mechanism common to all Great Lakes States and Tribes that could be used in setting permit limits for the Great Lakes System. This approach is consistent with the goals and purposes of the Great Lakes Critical Programs Act of 1990. Also, as explained in section II of the preamble, EPA wanted to give dischargers an incentive to conduct studies and develop data that would permit EPA to promulgate Tier I criteria for additional pollutants

To address the needs referenced above, the Steering Committee developed a Tier II methodology under which aquatic life values could be calculated with fewer than the eight taxonomic families of data required for a Tier I criterion calculation. This methodology may be found in sections XII through XVIII of appendix A to part 132. The purpose of this methodology is to provide Great Lakes States with guidance on evaluating pollutants from both point and nonpoint sources when there is insufficient data to develop a Tier I criterion.

The Steering Committee intended that the outcome of a Tier II analysis would be a somewhat conservative value to reflect the increased uncertainty surrounding a more limited database. This consideration resulted in the development of a methodology which produces more stringent (lower) values where there are fewer data and higher values as the database increases. EPA agrees that a uniform method will advance the goals of the Great Lakes Critical Programs Act of 1990, and is proposing the method that the Steering Committee developed.

EPA, on a long-standing basis, has recommended that an integrated approach to water quality-based toxics control be used. This integrated approach uses both chemical specific and whole effluent means for controlling discharges. Chemical specific water quality criteria and Tier II values reflect the concentration and dispersal of pollutants, or their byproducts, through biological, physical, and chemical processes, and the effects of pollutants on biological community diversity, productivity, and stability of the receiving water. A water quality standard defines the water quality goals of a water body, or portion thereof, by designating the use or uses to be made of the water, by setting criteria necessary to protect the uses, and by establishing antidegradation policies and implementation procedures that serve to maintain and protect water quality. On the other hand, whole effluent toxicity (WET) is a useful parameter for assessing and protecting against impacts upon water quality and designated uses caused by the aggregate toxic effect of the discharge of pollutants. In particular, the WET approach is used when the toxic agent is unknown within the effluent or possible chemical interactions are not understood.

One of the advantages to having chemical specific Tier II values is that facilities can design treatment to address a particular contaminant. For whole effluent toxicity, facilities have less knowledge of and experience in designing or manipulating treatment systems to treat the general parameter of toxicity.

Current EPA regulations at 40 CFR 122.44(d)(1) articulate when chemical-specific and whole effluent toxicity limits are required in a permit to meet State water quality standards, including both the narrative and numeric criteria. When the permitting authority determines that a discharge causes, has the reasonable potential to cause, or contributes to an excursion of the narrative criterion within the State water quality standards, the permit must contain limits for whole effluent toxicity. The only exception to this requirement is where the permitting authority demonstrates that chemical specific limits are sufficient to attain and maintain applicable narrative and numeric State water quality standards (40 CFR 122.44(d)(1)(v). Likewise, where the discharge of a particular pollutant causes, has the reasonable potential to cause or contributes to the excursion of a State's narrative criterion, the permit must contain effluent limitations to control the discharge of that pollutant (40 CFR 122.44 (d)(vi). These regulations provide three options ((A)–(C)) for interpreting the State's narrative criteria for purposes of deriving permit limits to control the pollutant(s) of concern. These three options focus primarily on the derivation of chemical specific limits, however, option (C) provides the opportunity to utilize controls on an indicator parameter or pollutant. Whole effluent toxicity can be used as an indicator parameter under this option.

In short, EPA regulations require the use of WET limits and chemical specific limits to protect the State's narrative water quality criteria, but also prescribe circumstances under which both types of limits are not necessary for a discharger that is or may be encroaching on the State's narrative criteria.

This NPDES regulation provides flexibility to States in deciding which option or combination of options to use in developing acceptable levels of discharge for the pollutants of concern. The Great Lakes States desire consistent implementation and application of all criteria, including the narrative criterion, across the basin. The approach used in the Great Lakes Initiative Guidance, is equivalent to requiring a criterion be derived using both options (A) and (C) of 40 CFR 122.44(d)(1)(vi), where the Tier II value will act as option (A) and WET as option (C). With this approach, States can ensure consistent implementation of the narrative criterion for water quality.

EPA recognizes that Tier II requirements for aquatic life and WET testing do overlap substantially. The Steering Committee, however, recommended requiring both methods to make regulation more uniform across the Great Lake States and to increase the level of protection for aquatic life in the Lakes. The Committee also expected the relatively stringent Tier II requirements to motivate some permittees to conduct enough testing to support development of less restrictive and more robust Tier I criteria.

EPA requests comment on the need for requiring limitations based upon Tier II values as well as using WET in place of a Tier II value, and other options for harmonizing the two requirements.

Elements of Michigan's "Rule 57" process were considered by the Steering Committee in developing the proposal for the Tier II methodology. "Rule 57" is a two-tiered approach for calculating regulatory values for toxic substances. In the absence of sufficient aquatic toxicity data for a Tier I calculation, this approach allows for calculation of an acute criterion by dividing the lowest acute value for either a *Daphnid* sp., rainbow trout, or fathead minnow by a factor appropriate for the species combination. These factors were derived from a statistical analysis developed by Michigan with the intent of producing a criteria that is more restrictive than one calculated with a Tier I database 80 percent of the time. A chronic value is calculated by dividing the acute

criterion by a laboratory derived or default acute-chronic ratio.

While the "Rule 57" Tier II approach answered the need for a method whereby a smaller database could be used to derive values, it used toxicity studies for only three species (rainbow trout, fathead minnow, and daphnids). Even if additional toxicity data existed for a given pollutant, those data would not be used to derive a Tier II value. The Initiative Committees sought a method that provided the option of utilizing all available, acceptable data for pollutants not meeting the Tier I data requirements (e.g., a method that utilized data on aquatic species from fewer than eight families).

Another methodology considered was EPA's draft "Guidelines for Deriving Ambient Aquatic Life Advisory Concentrations" (Office of Water Regulations & Standards, 1987), which is available in the administrative record for this rulemaking. This approach allowed the use of more data than "Rule 57." Acute values for one to twenty species of aquatic animals could be used to derive a value in place of a Tier I criterion. The 1987 draft Guidelines also applied factors to calculate conservative values and used assumed ACRs when there were not enough experimentally-derived ACRs. However, the adjustment factors in this method were not based on an analysis of empirical data, but chosen by using best professional judgment. The 1987 draft Guidelines were never actively used by EPA due to recommendations by the EPA's Science Advisory Board that the factors be statistically derived. Although the Initiative Committees favored the use of as much data as possible, the 1987 draft Guidelines were not chosen because of the severe drawback of not having statistically derived factors.

EPA considers the Tier II methodology proposed as part of the Great Lakes Guidance to be an improvement over the basic concepts within Michigan's "Rule 57" and the 1987 draft Guidelines. For the method proposed, elements of Michigan "Rule 57" and the 1987 draft Guidelines were expanded upon and components of studies described by Host, *et al.* (1991) in the draft paper, "Analysis of Acute and Chronic Data for Aquatic Life," were utilized. These documents are available in the administrative record for this rulemaking.

The Tier II methodology uses factors obtained in the statistical analysis described by Host, *et al.* (1991) to derive Tier II values from data for one to seven of the requisite eight taxonomic families necessary for Tier I calculations. Depending upon the number of Tier I minimum data requirements satisfied in the database, different adjustment factors are applied to the lowest Genus Mean Acute Value to arrive at the Secondary Acute Value (SAV). These adjustment factors are intended to relate the results of one to seven toxicity tests to a FAV.

In its December 16, 1992 report to EPA, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," EPA's Science Advisory Board (SAB) stated that it agreed with the concept of Tier I and Tier II criteria but was concerned that the minimal data base currently required in Tier 2 water quality criterion—a single aquatic toxicity test—is inadequate. (See section I.F of this preamble for further discussion of the SAB report.) States and Tribes sometimes need to regulate discharges, however, when a full complement of aquatic toxicity data (as specified in the Tier I method) is not available for a particular pollutant. The method proposed provides a consistent mechanism for the Great Lakes States to regulate those pollutants with little data. Although a Tier II value may be developed using a single aquatic toxicity test, EPA believes that few, if any, Tier II values, based on a single data point, would be derived for use in control mechanisms. The methodology requires States and Tribes to use as many acceptable data as exist. The State or Tribe could not arbitrarily choose a single aquatic toxicity test to derive a Tier II value if other data exist. The approach proposed requires the maximum amount of quality information to be utilized before any Tier II value can be derived. Moreover, EPA believes that information from one aquatic toxicity test, if properly conducted pursuant to the methods described in this Guidance, is sufficient to form the basis for a Tier II value to prevent interference with designated uses. EPA invites comment on whether the minimum data base required for Tier II aquatic life criteria is adequate.

The Science Advisory Board also suggested use of short term chronic toxicity tests to derive a Tier II value, overcoming the cost of completing standard chronic toxicity tests. EPA invites comment on whether it is appropriate to utilize short term chronic tests to derive Tier II values.

In its report the SAB also stated that there were some new fairly inexpensive short cut methods with some plants, invertebrates, and fishes which offer many advantages over acute data with extrapolations to chronic effects of other species. The SAB report gave no suggestions on specific methods. EPA could not evaluate this suggestion without further guidance on which methods the SAB specifically recommends. EPA invites comment on whether shortcut toxicity methods should be utilized to derive Tier II values and specifically asks for recommendations on specific methods.

The SAB did specifically recommend that the Mayer method of the "infinite LC Zero" should be considered as an alternative when there is only a single acute toxicity test for a given pollutant. This method, "Statistical Approach to Predicting Chronic Toxicity of Chemicals to Fishes from Acute Toxicity Test Data," is an approach to predicting chronic toxicity from acute toxicity data. Simultaneous consideration is given to concentration, degree of response, and time course of effect from an acute toxicity test. The method utilizes a consistent endpoint (lethality) and degree of response (zero percent) to predict chronic lethality from acute toxicity tests. The method assumes that concentration-response is a continuum in time, and the mode of action for lethality is similar under acute and chronic exposures. The method can predict growth effects from chronic lethality but is not intended to predict chronic reproductive effects. The literature supporting the method is available in the administrative record for this rulemaking. The corresponding software (PB 92–503119) and the supporting literature (PB 92–169655) may also be obtained through the National Technical Information Service (NTIS). EPA requests comment on the use of this method to develop chronic Tier II values and invites comment on alternative toxicity methods, to obtain data, for use in the Tier II methodology.

The "Analysis of Acute and Chronic Data for Aquatic Life," Host, *et al,* 1991 report presented several options for statistically developing adjustment factors using data from National criteria documents. In the proposed Guidance only one of those options is utilized. EPA solicits comment on the option chosen as well as the other options described in Host et al. For example, with the assumption of an 80th percent probability, these adjustment factors range from 242, when data from only one taxonomic family exists, to 7.2, when seven of the Tier I minimum data requirements are satisfied. These adjustment factors may be found in Host, et al, and its supporting documentation. "Analysis of Acute and Chronic Data for Aquatic Life" is available in the administrative record for this rulemaking. If a further restriction is made that one of the genera represented must be either "*Ceriodaphnia* sp", "*Daphnia* sp" or

"*Simocephalus* sp" the adjustment factors, assuming an 80 percent probability, range from 20.5, for one taxonomic family, to 3.6 where data for seven taxonomic families exist. Table III–3 lists the adjustment factors which result when different percentiles are assumed.

TABLE III–3.—Adjustment Factors

[With Daphnid Required]

Sample Size	Percentile						
	1	2	3	4	5	6	7
50	4.9	3.2	2.6	2.4	2.2	2.0	1.9
80	20.5	13.2	8.6	6.5	5.0	4.0	3.6
95	93.5	57.8	50.5	41.8	31.0	22.0	13.1

For the proposed Tier II approach, the Initiative Committees chose to use adjustment factors which required data for one of the three daphnid genera named above and also chose to use the 80th percentile. EPA is proposing to require the use of data from daphnids because they appear to be the most sensitive species for many pollutants of concern. The proposed choice of the 80th percentile by the Great Lakes Water Quality Initiative Steering Committee was a policy decision. It meant that 80 percent of the time, the calculated Tier II acute values would be at least as restrictive as a Tier I FAV if the minimum data requirements for a Tier I calculation were satisfied. The Steering Committee made the judgment that the adjustment factors associated with the 80th percentile were appropriate from a statistical and technical standpoint. EPA is unaware of information or data which would indicate that this judgment is unreasonable. EPA invites comment on the selection of an 80th percentile in establishing adjustment factors. Additionally, EPA invites comment on the use of factors "with daphnid data" as opposed to the higher adjustment factors that would be necessary if data for the specified daphnids are not required.

A separate statistical analysis, within "Analysis of Acute and Chronic Data for Aquatic Life" (Host, *et al.*, 1991), was used to derive a default ACR of 18. When fewer than three experimentally-derived ACRs exist, enough assumed ACRs of 18 would be used so that the total of the ACRs equals three. This acute-chronic ratio of 18 is also based on an 80th percentile to correspond with the adjustment factors chosen to derive the SAV. EPA requests comment on the use of assumed ACRs in place of experimentally derived ACRs, and particularly on the use of 18 as the default ACR.

The Tier II methodology proposed employs all appropriate toxicity data available for a pollutant, uses statistically derived adjustment factors based on existing National criteria, and produces values which are generally conservative relative to a comparable Tier I criterion. Sample calculations of Tier II values are available in the administrative record for this rulemaking. EPA invites comment on acceptable alternatives to a tiered approach. EPA also invites comments on the approach proposed as well as alternatives.

D. Conformance to the Clean Water Act, Great Lakes Water Quality Agreement and Great Lakes Critical Programs Act of 1990

Section 118(c) of the Clean Water Act requires EPA to develop, *inter alia*, guidance on minimum water quality limits to protect human health, aquatic life and wildlife in the Great Lakes System. The CPA states that the proposed Guidance shall be no less restrictive than the provisions of the Clean Water Act, National water quality criteria and National guidance, and shall conform with the objectives and provisions of the Great Lakes Water Quality Agreement.

1. Tier I Aquatic Life Criteria and Methodology

a. Comparison With the Clean Water Act. Section 304(a)(1) of the CWA authorizes EPA to develop and publish criteria for water quality accurately reflecting the latest scientific knowledge on the kind and extent of all identifiable effects on, among other things, health and welfare, including plankton, fish, and shellfish, which may be expected from the presence of pollutants in any body of water, 33 U.S.C. 1314(a)(1). Under this authority, EPA developed provisions for deriving water quality criteria for waterbodies nationwide. These provisions are contained in the 1985 "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses." The proposed Guidance on Tier I aquatic life criteria methodology, as well as the criteria proposed thereunder, are based on and are consistent with the 1985 National Guidelines. EPA believes that, although they are not identical to the 1985 Guidelines and individual National criteria in all details, they are generally no less restrictive.

First, as discussed above in this section of the preamble, EPA has not proposed Tier I aquatic life criteria for eleven pollutants for which National criteria exist (aldrin, chlordane, DDT, endosulfan, heptachlor, PCBs, lead, toxaphene, aluminum, silver and chlorpyrifos). EPA is also proposing to require as part of the Great Lakes Guidance only an acute criterion for lindane, although there are National criteria for both acute and chronic effects. EPA believes that these decisions, however, will not result in less stringent control of these pollutants. Under the implementation scheme proposed, Great Lakes States and Tribes would be required to derive values for these pollutants using the Tier II method whenever the State or Tribe determines that it is necessary to control any of these pollutants. The State or Tribe would have to compare the Tier II value to any existing State criteria for the same pollutant. If the Tier II value is more stringent, the Tier II value would supersede the existing criterion and the Tier II value would be used to derive permit limits and other control mechanisms. (If the existing criteria is more stringent, the State or Tribe would have the option of using either number.) As described elsewhere in this preamble, the Tier II method derives conservative values to compensate for a limited data base. Consequently, EPA expects that Tier II values will be more stringent than existing standards for

these pollutants in eighty percent of all cases.

Furthermore, all but four of Tier I criteria for aquatic life proposed are equivalent to or more restrictive than the current National criteria. EPA believes that the proposed Tier I criteria for cadmium, chromium III and zinc are not significantly less restrictive than the existing National criteria because the differences between these proposed criteria and the National criteria are minor. Furthermore, EPA believes that the proposed criteria are more appropriate because they are based on more recent data. EPA, however, requests comment on the option of promulgating the National criteria for those pollutants which have more stringent National criteria values.

The difference between the proposed criterion and current National criteria for protection against the chronic effects of mercury is considerably larger. Nonetheless, EPA believes that overall protection will not be reduced. The chronic aquatic life criterion for mercury became less restrictive than the current National criterion when EPA eliminated all consideration of Final Residue Values data from the calculation of the criterion. As explained earlier, EPA is proposing to delete Residue Values from all aquatic life criteria for the Great Lakes because it is proposing separate, specific wildlife criteria in the proposed Guidance. EPA is proposing a wildlife criterion for mercury of 180 μg/L (or 0.00018 μg/L) that is more restrictive than the National chronic aquatic life criterion for mercury (0.012 μg/L). Since both the aquatic life and the wildlife criteria will apply in all portions of the Great Lakes basin, EPA believes that protection will be maintained.

b. *Conformance With the Great Lakes Water Quality Agreement.* A comparison of the Tier I criteria proposed herein with the pollutants for which the Agreement specifies a numeric standard for a specified pollutant/parameter reveals that, in all but a few cases, the Agreement's standards are more conservative. EPA nevertheless believes that the numeric criteria in the proposed Guidance, as well as the methodology upon which they were derived, conform with the provisions and objectives of the Agreement. This position is based on the fact that the current Agreement, in EPA's opinion, needs revision. The current criteria in the Agreement, created in 1978 as "interim" numbers, were for the most part a result of negotiation. EPA has not been able to find any record revealing their technical or policy bases. Further, EPA believes that the standards on the Agreement were not developed in consultation with the States or Tribes. The numeric criteria in the proposed Guidance are based on sound scientific criteria development methodology and are proposed after consultation with the States, as required by the Supplement to Annex I to the Agreement's Specific Objectives.

EPA also believes that Congress did not intend to compel EPA to replicate the pollutant concentrations for the protection of aquatic life set out in Annex 1 to the Agreement. Section 118(c)(2)(A) of the CWA directs EPA to develop numeric limits on pollutants in the Great Lakes waters, but leaves the selection of the limits to EPA's discretion. EPA believes that Congress would have been very explicit if it had intended to deprive EPA of the authority to exercise its own judgment on the technical and scientific issues involved. Moreover, the legislative history shows that Congress knew and approved of the ongoing work of the Great Lakes Initiative Committees. S. Rep. 101–339, 101st Cong., 2d Sess. at 18 (June 27, 1990); 136 Cong. Rec. S15616 (Oct. 17, 1990) (remarks prominently on the committees' work, it is reasonable to assume that Congress expected EPA to develop its own criteria). Consequently, EPA does not believe that "conformance" with the Agreement requires the numeric criteria proposed to be identical to or no less restrictive than individual Annex 1 values. Rather, EPA's guidance must conform with the more general objectives of the Agreement regarding the elimination or reduction to the maximum extent practicable discharges into the Great Lakes System. The criteria and methodologies proposed in the proposed Guidance conform with this objective. Further, as explained above, EPA cannot evaluate the technical basis for the Agreement's standards. EPA reasonably prefers to propose standards which are supported by extensive record.

EPA believes that the position taken by the Initiative Committees to the Guidance criteria and methodologies proposed herein could serve as a basis to amend and supplement the Great Lakes Water Quality Agreement is reasonable. Besides being consistent with the terms of the Agreement, which require the United States to, after consultation with the States, revise and supplement the Specific Objectives included therein, it is also consistent with the intent of the CPA.

2. Tier II Criteria Methodology

a. *Comparison With the Clean Water Act.* EPA's current guidance and regulations for water quality standards contain nothing directly analogous to the Tier II methodology and values proposed for aquatic life. Rather, under the existing program many States and tribes interpret narrative criteria on a case-by-case basis to ensure that discharges of pollutants that lack numeric criteria will not adversely affect human health or the environment. Other States and Tribes develop their own numeric criteria based on methods requiring less data than the existing National criteria guidance requires. The Tier II methodology and values proposed would not be less restrictive than this existing approach. In the first place, EPA expects that eighty percent of the Tier II values that the States and Tribes derive will be more restrictive than the State and Tribal standards that EPA could approve for the same pollutants under the current CWA program because the adjustment factor incorporated into the Tier II approach, as proposed, imposes more structure on the process of translating narrative criteria into numeric values. States and Tribes currently have very broad discretion when regulating pollutants that are subject only to narrative criteria. The proposed Guidance is more rigorous than the current National requirements in this area. Finally, the proposed approach will result in more uniform control of pollutants lacking National criteria in the Great Lakes States and Tribes.

b. *Conformance With the Great Lakes Water Quality Agreement.* Tier II is a conservative methodology designed to establish environmentally protective limits on the discharge of pollutants into the Great Lakes System. The methodology will result in the regulation of the discharge of certain pollutants which heretofore in certain Great Lakes States may have gone unregulated by a specific numeric criteria, instead being regulated by narrative criteria or by indicator pollutants such as biological oxygen demand (BOD). The Tier II methodology is consistent with the purpose of the Agreement, "to eliminate or reduce to the maximum extent practicable the discharge of toxic substance in toxic amounts" and serves as a translator mechanism of the Agreement's narrative standards found in the General Objectives, Section D, Article III. The Tier II methodology will enhance regulatory efforts in the Great Lakes basin, will serve its purpose of promoting consistency in the regulation of toxics in the Great Lakes basin, and is therefore also in conformance with the Agreement.

IV. Bioaccumulation Factors

A. Introduction

Aquatic organisms, exposed to certain types of chemicals, will accumulate those chemicals in their bodies. Chemical uptake is due to exposure from the water the organisms live in, the food they eat, and other sources of the chemical. This process is called bioaccumulation. For certain chemicals, uptake through the food chain is the most important route of exposure. As lower trophic level organisms are consumed by higher trophic level organisms, the tissue concentrations of these chemicals may increase with each trophic level so that residues in top carnivores may be many orders of magnitude greater than the concentration of the chemical in the environment. While the exposure concentration in the environment may be too low to affect the lowest level organisms, this biomagnification process can result in severe health effects for the consumers of top trophic level aquatic organisms.

For the purpose of the Great Lakes Guidance, bioaccumulation factors have been developed to reflect the propensity of an organism to accumulate a chemical in its tissues, when exposure to the chemical is from all sources including food and water. Bioaccumulation factors serve several purposes in the Guidance.

First, in order to properly account for potential exposure to a chemical, both the wildlife criteria and the human health criteria have been developed to be a function of the bioaccumulation factor. That is, for example, all else being equal, if two chemicals have different bioaccumulation factors, the chemical with the higher bioaccumulation factor will have the lower criterion. Thus, prior to deriving a human health or a wildlife criterion, a bioaccumulation factor for the chemical must be established.

Secondly, within the Great Lakes System both wildlife and humans may be susceptible to adverse health effects from chemicals which are highly bioaccumulative. While not the only indicator of a chemical's potential harm, the bioaccumulation factors are believed to be an indication of which chemicals may be of greatest concern within the Great Lakes System. Thus, the human health bioaccumulation factors have been used to identify a list of chemicals which warrant increased attention, and more stringent controls, within the basin. In this Great Lakes Water Quality Initiative (GLWQI), these chemicals are called the Bioaccumulative Chemicals of Concern (BCCs). See Discussion of BCCs in section II.G above.

B. Bioaccumulation Factors

The proposed Great Lakes Guidance methodology for developing bioaccumulation factors (BAFs) is discussed below. The proposed Guidance on bioaccumulation is compared to existing National guidance and practices, and differences are discussed. Throughout the discussion, issues for which EPA specifically invites comment are highlighted.

The procedure for developing the bioaccumulation factors is included in appendix B of part 132 of the proposed Guidance. Great Lakes Water Quality Initiative Technical Support Documents, which further discuss the basis for the proposed Guidance and which provide the data and considerations upon which the BAFs are based, are identified below and are available in the administrative record for this rulemaking. Copies are also available upon written request to the person listed in section XIII of this preamble.

Finally, EPA's expectations for determining whether a State's water quality standards are consistent with the Guidance are set forth in § 132.6 of the proposed Guidance and discussed in section II.I of this preamble.

1. Bioaccumulation and Bioconcentration Concepts

Bioaccumulation refers to the uptake and retention of a substance by an aquatic organism from its surrounding medium and food. A bioaccumulation factor (BAF) represents the ratio (in L/kg) of a substance's concentration in tissue to its concentration in the surrounding water in situations where both the organism and its food are exposed and the ratio does not change substantially over time. Field measured BAFs are based on field data.

A steady-state bioconcentration factor (BCF) is the uptake and retention of a substance by an aquatic organism from the surrounding water only, through gill membranes or other external body surfaces. Laboratory measured BCFs are the result of laboratory experiments using aquatic organisms. In this preamble, methodology, and Technical Support Document, wherever the term BCF is used, steady state is implied.

2. Existing EPA Guidance

EPA, in developing criteria to protect humans and wildlife from the consumption of contaminated aquatic organisms, has relied upon the BCF and occasionally BAF to relate water concentrations to the amount of a contaminant that is ingested. The BAF is ideally the best factor to use because it accounts for the uptake by aquatic organisms of a chemical from all sources including diet, sediments, and the water itself. However, EPA has also recognized the difficulties in deriving scientifically valid BAFs. BAFs are a scientific area which is still evolving. This is exemplified by EPA's past and current guidance. For example, EPA's 1985 "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses" (1985 National Guidelines), states:

> * * * although BCFs are not too difficult to determine, very few BAFs have been measured acceptably, because it is necessary to make enough measurements of the concentration of the material in the water to show that it was reasonably constant over a long period of time, over the range of territory inhabited by the organisms.

This document is available in the administrative record for this rulemaking. Copies are also available upon written request to the person listed in section XIII of this preamble.

Because of the difficulty in deriving BAFs, most of the existing human health and aquatic life National criteria are based upon BCFs. BAFs reported in the scientific literature need to be carefully evaluated to ensure that they adhere to the criteria of acceptability outlined in EPA's 1985 National Guidelines methodology.

Bioconcentration factors are determined either by measuring bioconcentration in laboratory tests (comparing fish tissue residues to chemical considerations in test waters), or by predicting the BCF from a chemical's octanol-water partition coefficient (K_{ow} or P). The log of the octanol-water partition coefficient (log K_{ow} or log P) has been shown in the scientific literature to be empirically related to the bioconcentration factors (e.g. Mackay, 1982; Connell, 1988; Veith et al., 1979).

In 1980, EPA issued its "Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents" (45 FR 79341, November 28, 1980). These guidelines serve as the basis for nearly all of the current National human health criteria. In these guidelines, the following equation (Equation 1) is used to predict BCFs for organic chemicals in the absence of laboratory measured BCFs (Veith et al., 1979).

Equation 1:

$$\log BCF = 0.85 \log K_{ow} - 0.70$$

More recently, in 1991, EPA issued the final "Technical Support Document for Water Quality-based Toxics Control" (EPA 505/2–90–001) and a draft document entitled "Assessment and Control of Bioconcentratable Contaminants in Surface Waters" for notice and comment (56 FR 13150), which are available in the administrative record for this rulemaking. These documents, relying on additional research into the relationship between BCF and log K_{ow}, recommend that a slightly different equation (Equation 2) be used to derive BCFs in the absence of laboratory measured BCFs (Veith and Kosian, 1983).

Equation 2:

$$\log BCF = 0.79 \log K_{ow} - 0.40$$

This equation is used to estimate BCFs in EPA's computerized Quantitative Structure Activity Relationships (QSAR) database, and is also the equation proposed for use in the proposed Guidance.

EPA's 1991 National guidance documents, the Technical Support Document for Water Quality-based Toxics Control" and draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters", recommend a methodology for estimating the BAF where there is an absence of a field-measured BAF. This methodology multiplies the BCF by a factor which accounts for the biomagnification of a pollutant through trophic levels in a food chain. As larger predatory aquatic organisms, such as pike, consume other fish and aquatic organisms, the amount of some contaminants in the consumed fish is concentrated in the predator. The factor which accounts for this biomagnification through the food chain is called the food chain multiplier (FCM) in these 1991 National guidance documents. EPA calculated the FCMs using a model of the step-wise increase in the concentration of an organic chemical from phytoplankton (trophic level 1) through the top predatory fish level of a food chain (Thomann, 1989).

The FCMs were determined by first running Thomann's model to generate BCFs and BAFs for trophic level 2, and BAFs for trophic levels 3 and 4. This was done for a range of log K_{ow} values from 3.5 to 6.5, at intervals of a tenth of log K_{ow} value. Second, the FCMs for each log K_{ow} value in this range were calculated using the following equations:

For trophic level 2 (zooplankton):

$$FCM = \frac{BAF2}{BCF2}$$

For trophic level 3 (small fish):

$$FCM = \frac{BAF3}{BCF2}$$

For trophic level 4 (top predator fish):

$$FCM = \frac{BAF4}{BCF2}$$

Where:

BCF2 is the BCF for trophic level 2 organisms, and BAF2, BAF3 and BAF4 are the BAFs for trophic levels 2, 3, and 4, respectively.

The resulting FCMs for trophic levels 2, 3, and 4 are shown in Table B–1 of appendix B of part 132 for log K_{ow} values ranging from four to 6.5.

Thomann (1989) compared predicted BAFs for trophic level 4 with measured BAFs from the Great Lakes and concluded that, within an order of magnitude, the model-predicted BAFs were a reasonable representation of the observed data for chemicals with log K_{ow} values in the range of 3.5 to 6.5.

At log K_{ow} values of 6.5 and greater, the relationship between log K_{ow} and the FCM is less certain, for reasons described in section IV.B.3.c of the preamble. Existing EPA guidance recognizes that FCMs may range from 0.1 to 100 for such chemicals, and provides that a FCM of 100 could be used as a conservative standard value in the absence of chemical-specific BAF information.

EPA evaluated its own BAF prediction procedure using field studies, as reported in appendix I of the draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters" guidance document. In these field studies, residues in receiving water organisms were predicted using EPA's BAF prediction procedure and were then compared to the measured tissue residues. These studies demonstrated acceptable agreement between measured and predicted tissue residues which, therefore, demonstrated that EPA's BAF prediction procedure provides acceptable BAF values. The results of this EPA evaluation are presented in detail in two EPA field studies (Burkhard et. al. 1991, 1992), which are available in the administrative record for this rulemaking.

3. The Great Lakes Guidance for BAFs

The bioaccumulation concepts contained in the proposed Guidance, data supporting these concepts, and additional details are also discussed in the GLWQI Bioaccumulation Factors Technical Support Document, which is available in the administrative record for this rulemaking. Proposed § 132.4(a)(3) requires the use of the BAF methodology in appendix B of part 132 in the derivation of criteria for protecting humans and wildlife. EPA believes that the BAF is the best predictor of the concentration of a chemical within fish tissue in the Great Lakes because it includes consideration of the uptake of contaminants from food, sediments, and the water itself; and is, therefore, the most appropriate factor for the developing criteria. In the past, EPA has rarely used the BAF to develop criteria due to the lack of reliable field data. However, EPA now believes that the BAF can be approximated from BCF data and information concerning biomagnification through the food chain.

a. *Measured and Predicted BAFs.* The proposed Guidance lists three methods to derive BAFs for non-polar organics, listed below in order of preference: A BAF measured in the field, preferably in fish collected from the Great Lakes which are at the top of the food chain; a BAF predicted by multiplying a BCF measured in the laboratory, preferably (but not required) on a fish species indigenous to the Great Lakes, by the food chain multiplier; and a BAF predicted by multiplying a BCF calculated from the log K_{ow} (using Equation 2) by the food chain multiplier.

Measured BCFs for organics can be determined in several ways. These include analytical measurements of tissue and water using gas chromatography (GC) or high pressure liquid chromatography (HPLC). Another method for determining a laboratory-measured BCF is to use radio labeled organic chemicals. However, the radio labeled compound leaves open a possibility of error in several areas. In radio labeling, the organism may metabolize a metabolite of the parent compound thereby inflating the measured BCF. There is also a possibility of contamination of the labeled compound.

For inorganic chemicals, either a measured BAF or BCF must be used. This is because no method is available for reliably predicting BCFs or BAFs for inorganic chemicals; BCFs and BAFs vary from one invertebrate to another, from one fish to another, and from one tissue to another within a species. As reported in the "GLWQI Bioaccumulation Factors Technical Support Document", which is available in the administrative record for this

rulemaking, accumulation of inorganics varies significantly between species and types of tissues.

EPA invites comment on: How to predict a BCF from log P; the acceptable methods for measuring BCFs with radio labeled organic compounds which could inflate the measured BCF, as opposed to BCFs more conventionally measured using gas chromatography or HPLC; whether a BCF is preferable to measured or predicted BAFs as proposed; the derivation of BAFs for inorganic chemicals such as mercury and selenium; and the GLWQI methods for developing a value for a BAF and the preferred order. In addition, in its December 16, 1992 report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," EPA's Science Advisory Board (SAB) stated that:

> Field BAFS must be interpreted very carefully, and it should be recognized that they may contain substantial errors and variability due to the following reasons: (1) Analytical methodologies generally determine total concentrations all of which may not be biologically available; (2) There may be a loss of analyte by sorption or evaporation during sampling; (3) Incomplete extractions may occur, especially if there is a high organic carbon content in the water; (4) Temporal and spatial variability in water concentrations; (5) Variability in fish concentrations due to size, age, sex, etc.

EPA agrees that these are valid considerations for selection of field-measured BAFs and invites comment on whether appendix B of part 132 should provide more guidance on the quality of acceptable data, and what additional factors should be reviewed for acceptability of data.

b. *Standard Lipid Values.* Consistent with the existing National guidance, the proposed Guidance relies on the fundamental assumption that an organism's ability to bioaccumulate organic chemicals is proportional to its lipid content. For example, an organism with a two percent lipid content would accumulate twice the amount of a chemical as an organism with a one percent lipid content, all else being equal.

In order to determine a BAF for organic chemicals, for use in deriving wildlife and human health criteria, it is necessary to know the percent lipid content of the organisms being consumed. The proposed Guidance proposes that standard lipid values higher than the three percent recommended for human health in EPA's 1991 "Technical Support Document for Water Quality-based Toxics Control" be used to represent the percent lipid content of the fish and other aquatic organisms consumed by humans and wildlife in the Great Lakes basin. Fish consumption patterns differ widely around the United States, and this is especially true in the Great Lakes basin. Humans also typically eat fish fillets which generally have lower lipid content than the whole fish generally consumed by wildlife. Therefore, standard lipid values have been developed separately for humans (5.0 percent) and for wildlife (7.9 percent). The rationale behind the selection of these standard lipid values for humans and wildlife is discussed below.

i. *Standard Lipid Value for Human Health BAFs.* The proposed Guidance proposes a standard lipid value of 5.0 percent in edible tissue for use in determining human health BAFs for organic chemicals. Percent lipid data for edible tissue (mostly skin-on fillets) were gathered from the fish contaminant monitoring programs in Michigan, Wisconsin, Ohio, Indiana, New York and Minnesota. These data are summarized in the BAF Technical Support Document. Lipid values for skin-on fillets are likely to be higher than lipid values for skinless fillets. Skin-on fillets typically include a layer of fatty tissue between the skin and muscle. The skin-on fillet is the tissue sample used by most of the Great Lake States' fish consumption advisory programs, and, therefore, the bulk of available data are for skin-on fillets. However, many anglers remove the skin and other fatty tissue when they prepare their fish for cooking. Consumption advisories recommend this practice. Therefore, use of skin-on data to determine the standard lipid values will provide an extra margin of safety to the many anglers who remove the skin from the fillet.

In selecting the standard lipid value for human health BAFs, the Technical Work Group considered lipid data for the following fish groups: Lipid data for salmonids (trout and salmon) only; lipid data for salmonids and non-salmonid game fish (perch, walleye, bass, etc.); and lipid data for all fish (game and nongame species).

Mean lipid values and standard deviations for each of the options are: 6.73±3.27 for salmonids; 5.02±3.55 for all game fish; and 5.25±3.68 for all fish. The Technical Work Group proposed to use the value for all game fish of 5.02 because this option best represented the range of species typically consumed by people in the Great Lakes basin.

The Technical Work Group also considered mean lipid values weighted by human consumption patterns, and the typical weight of sport-caught game fish by species. Consumption was addressed through creel survey data from the Great Lakes, and typical species weights from the State contaminant programs. The resulting overall consumption weighted mean for all game fish was 4.72 ± 2.42 percent lipid. Because these results were not different statistically from the means of the unweighted data, the Initiative Work Group proposed to use the unweighted mean value of 5.02 percent for the human health BAFs.

ii. *Standard Lipid Value for Wildlife BAFs.* The proposed Guidance proposes a standard lipid value of 7.9 percent for wildlife BAFs, based on consumption of whole fish. The standard lipid value for the wildlife BAFs was determined using whole fish lipid data from the U.S. Fish and Wildlife Service National Contaminant Biomonitoring Program and the Canadian Department of Fisheries and Oceans. These data are summarized in appendix B of the BAF Technical Support Document. The 7.9 percent lipid value is the mean of lipid values for all fish, game and nongame, in all of the Great Lakes. Data for all fish were used because wildlife typically are nondiscriminatory consumers of fish.

iii. *Comments requested.* EPA invites comments on the standard percent lipid values proposed in the proposed Guidance. Specifically, comments should address whether the trophic levels chosen to derive the human health and wildlife standard percent lipid values are appropriate, or the consumption-weighted human health value of 4.7, should be used in lieu of the 5.0 percent lipid value currently proposed. In addition, to the extent that the currently proposed values of 5.0 and 7.9 percent lipid overestimate mean lipid values of fish consumed by Great Lakes humans and wildlife, use of the values will provide a margin of safety. EPA specifically solicits comment on whether such a margin of safety is necessary. The data on which the mean percent lipid values are based were obtained by measuring percent lipids using a variety of solvents. The value of percent lipid obtained will depend to some extent on the solvent used. It has been shown that the analytical method used to determine percent lipid can affect lipid values because different solvent systems extract different fractions of total lipids (Randall et al., 1991). EPA invites comment on what solvent should be used in the measurement of percent lipids.

c. *Food Chain Multipliers.* As discussed above, EPA proposes to use food chain multipliers (FCM), based on a biomagnification model, to derive BAFs for organic chemicals when field studies do not exist. Food chain multipliers derived from the model

range from less than one to 100. Under the proposed Guidance, FCMs greater than one would usually apply to organic chemicals with log K_{ow} values in the range of 4.0 to 6.5. The FCMs which result from the Guidance proposed are listed in Table B–1 of appendix B of part 132.

In the proposed Guidance, when BAFs for human health are derived from BCFs through the application of a FCM, the appropriate FCM based on the chemical's log K_{ow} is selected from the trophic level 4 column in Table B–1 of appendix B of part 132. This assumes that humans typically eat trophic level 4 (top carnivore) fish species. For wildlife BAFs, FCMs from trophic levels 3 and 4 are used, and BAFs for invertebrates or aquatic plants may be used on a case-by-case basis (see Methodologies for the Development of Wildlife Criteria and Values in appendix D to part 132).

For chemicals with log K_{ow} values greater than 6.5 (superlipophilic chemicals), existing EPA guidance recommends FCMs in the range of 0.1 to 100 due to the uncertainty of predicting bioaccumulation for this group of chemicals (U.S. EPA 1991). For example, at the low end of this range, FCMs of 0.1 may be appropriate for some chemicals such as superlipophilic polycyclic aromatic hydrocarbons. These chemicals are metabolized rapidly by many fish, and not only is uptake through the food chain negated as a result, but rapid metabolism can result in bioaccumulation less than predicted using bioconcentration models such as Equation 2 (Niimi and Dookran, 1989).

In contrast, at the high end of the range, use of a FCM (at 5.0 percent lipid) of 100 provides a reasonable estimate of a measured BAF for octachlorostyrene (log K_{ow}=7.94). The mean of two measured BAFs (0.9 and 4.3 million) for this chemical is 1.9 million (Oliver and Niimi, 1985; Oliver and Niimi, 1988). The predicted BAF based on measured BCFs times a FCM of 100 is 6.6 million. The factor of 3.5 difference between measured and predicted BAFs indicates a FCM of 100 for this chemical is reasonable. The BAF for 2,3,7,8–TCDD of 50,000 (5.0 percent lipid) is an example of a superlipophilic chemical (log K_{ow}=7.36) with a FCM of about one.

From the above examples, it is clear that predicting the food chain biomagnification of superlipophilic chemicals is difficult. For this reason, the proposed Guidance recommends that chemical-specific data be used to determine the FCM for this group of chemicals. However, if no chemical-specific data are available, the Steering Committee proposed a FCM of one for superlipophilic chemicals as a standard value.

EPA invites comment on: the basic premise that a BCF may overestimate or underestimate a BAF; the appropriateness of FCMs based on the Thomann model; the appropriateness of using a FCM of one when chemical-specific values for superlipophilic chemicals are not available; and possible alternatives to the Thomann model for predicting BAFs from BCFs.

d. *Effect of Metabolism on BAFs.* Many organic chemicals that are taken up by aquatic organisms are transformed to some extent by the organism's metabolic processes, but the rate of metabolism varies widely from one chemical to another. For most organic chemicals, metabolism increases the depuration rate and reduces the BAF. However, metabolism does not always result in a lower BAF. Because they are based on field measurements, measured BAFs automatically take into account any metabolism that occurs. Predicted BAFs that are obtained by multiplying a measured BCF by a FCM automatically take into account the effect of metabolism on the BCF, but do not take into account the effect of metabolism on the FCM. Predicted BAFs that are obtained by multiplying a predicted BCF by a FCM make no allowance for metabolism.

Available information indicates that some organic chemicals, such as polynuclear aromatic hydrocarbons (PAHs), are metabolized by aquatic organisms, but that the extent of that metabolism varies substantially from one PAH to another and from one species to another. The available information, accordingly, is not amenable to a general prediction of the effect of metabolism on the magnitude of the BCF, FCM, or BAF.

For these reasons, the BAF methodology being proposed for organic chemicals includes a provision that

> Both human health and wildlife BAFs should be reviewed for consistency with all available data concerning the bioaccumulation of the chemical. In particular, information on metabolism, molecular size, or other physicochemical properties which might enhance or inhibit bioaccumulation should be considered. The BAFs may be modified if changes can be justified by the data. (section VI.D.5 of appendix B of part 132)

EPA expects States and Tribes to follow this guidance on a site specific basis if necessary in developing the BAFs used for developing human health and wildlife criteria and values.

One approach that might be usefully applied to individual organic chemicals for which a measured BAF is not available but for which a measured BCF is available is as follows. If metabolism affects the BCF, the measured BCF will usually be lower than would be predicted on the basis of log K_{ow}. The relationship between log K_{ow} and BCF for non-metabolized chemicals can be used to back calculate an "effective log K_{ow}" from the measured BCF. An "effective FCM" can then be based on the "effective log K_{ow}." A predicted BAF that takes into account metabolism can then be obtained by multiplying the measured BCF by the "effective FCM." This approach would provide an allowance for metabolism for organic chemicals for which a measured BCF is available but for which a measured BAF is not available.

EPA solicits comment on: Suggested methods to adjust predicted BAFs for chemicals that are metabolized; the types of chemicals or chemical groups for which the BAF might be affected by metabolism, and the possible use of an "effective FCM", as described above, to account for metabolism when measured BAFs are not available, but measured BCFs are available; and any other alternative methods not explicitly described above.

e. *Bioavailability.* The predicted human health and wildlife BAFs for organic chemicals are based on the total concentration of the chemical in water. For highly lipophilic chemicals, however, a substantial percentage of the total concentration can be associated with particulate and dissolved organic matter in water and be unavailable for accumulation. Thus, the bioavailability of the chemical in water might vary with the organic carbon content of the water. Even in "clean" laboratory water, a substantial percentage of a chemical with a Log P of seven can be associated with organic matter in the water. Application of BAFs to a site might, therefore, be improved by adjusting for the difference in bioavailability between the site water and the water on which the predicted BAFs were based. This might best be done by deriving BAFs in terms of "freely dissolved" chemical, i.e., that which is dissolved and not associated with other organic matter. The concentration of freely dissolved chemicals will usually have to be predicted, but it might be measurable in some cases.

EPA invites comment on: The merit of the above approaches for refining the predicted BAFs, in light of the fact that standard lipid values, FCMs and measured and predicted BAFs do not take into account bioavailability and

partitioning; and any additional recommendations for dealing with bioavailability and partitioning of chemicals of concern.

f. *Other Uses of BAFs.* In the proposed Guidance, BAFs are used to identify chemicals of greatest concern within the Great Lakes basin. Chemicals identified as Bioaccumulative Chemicals of Concern (BCCs) are those for which extra controls are necessary as specified in the proposed implementation procedures and under the antidegradation procedures in the proposed Guidance. See discussion of BCCs in section II.G, above.

EPA invites comment on: Other approaches which might be used to identify pollutants of greatest concern to the Great Lakes (e.g., chemical release and production data plus chemical toxicity and persistence); and the use of BAFs to identify these pollutants of greatest concern.

4. SAB Comments

In its December 16, 1992 report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," EPA's Science Advisory Board (SAB) reviewed the Initiative's draft BAF methodology prepared in December 1991. The SAB found that the BAF procedure is more advanced and scientifically credible than existing BCF procedures, and that the use of the BCF, FCM, and BAF approach appear to be fundamentally sound. The SAB made a number of comments, suggestions, and recommendations, however, concerning elements of the draft BAF methodology. One of the specific recommendations is discussed above (section IV.B.3.a of this preamble). Other SAB comments concerned the following areas: use of the Thomann model or suggested alternatives, metabolism, superlipophilic chemicals, the bioavailable form of a metal (mercury and selenium), and additional equations relating BCF to log P.

In preparing the BAF methodology and this section of the preamble for the publication of the proposed Guidance, EPA has revised the methodology and clarified the discussion of issues since the time of the SAB's review to address many issues including those raised in the SAB's final report. In those revisions, EPA added additional information and discussion of several issues. Many of the revisions were in response to informal comments from the SAB, the draft SAB report, and the final SAB report. Nevertheless, EPA invites comment on all of the issues raised by the SAB concerning the BAF methodology, including comment on specific suggestions for improving the methodology.

5. Relationship of the Guidance to Current EPA Guidance

Section 118(c)(2)(A) of the Clean Water Act requires that the Great Lakes Water Quality Initiative (GLWQI) Guidance be no less restrictive than the Clean Water Act and National water quality criteria and guidance, and conform with the objectives and provisions of the Great Lakes Water Quality Agreement (the "Agreement"). The GLWQI Guidance proposes four essential differences from existing EPA guidance in the bioaccumulation area. First, criteria are derived using field-measured or predicted BAFs rather than BCFs, as in existing section 304(a) criteria guidance. This change will result in more stringent criteria for most, if not all, chemicals in the Great Lakes, and is consistent with EPA's existing guidance ("Technical Support Document for Water Quality-based Toxics Control" (EPA 505/2–90–001) and draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters" (56 FR 13150)). Second, the hierarchy of preferred methods to obtain a BAF reverses the recommended order in the 1991 draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters". EPA anticipates making a similar change to its final "Assessment and Control of Bioconcentratable Contaminants in Surface Waters."

Third, the "Guidelines and Methodology Used in the Preparation of Health Effects Assessment Chapters of the Consent Decree Water Criteria Documents" (45 FR 79341, November 28, 1980), the 1991 "Technical Support Document for Water Quality-based Toxics Control", and the draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters" used three percent lipid for human health BAFs versus the 5.0 and 7.9 percent used for human health and wildlife BAFs in the GLWQI Guidance, respectively. This change will result in more stringent criteria for organic chemicals in the Great Lakes, and is justified in light of Great Lakes-specific data on fish lipid values.

The fourth issue relates to the lipid/BAF relationship for superlipophilic chemicals. The ability to predict bioaccumulation is poor for organic chemicals whose log K_{ow} is greater than 6.5. Such chemicals are called superlipophilic because of their very strong affinity for lipids. Certain factors, however, have been shown to inhibit the bioaccumulation of superlipophilic chemicals. These include the chemicals' very low solubility in water and the inhibition of molecular transport due to the large size of the molecules. Because of this, use of a FCM to derive a BAF may result in an overestimation of the bioaccumulation of these superlipophilic chemicals.

Current EPA guidance ("Technical Support Document for Water Quality-based Toxics Control") states that the FCM for superlipophilic chemicals can vary between 0.1 and 100, and provides that a FCM of 100 may be used for the top predator trophic level in the absence of chemical-specific information. The proposed Guidance recommends a FCM of 1 in the absence of chemical specific data. (In other words, the BAF equals the BCF unless chemical specific data are available.) Current EPA guidance ("Technical Support Document for Water Quality-based Toxics Control") recommends a range of values, and the proposed Guidance, with additional data, recommends a specific default value of 1.

EPA is soliciting: bioaccumulation data on any superlipophilic chemical listed in appendix A of part 132 of the GLWQI Technical Support Document; suggested techniques for deriving a BAF for superlipophilic chemicals, in the absence of chemical-specific data; and a recommended alternative FCM value (in lieu of the proposed value of one) for superlipophilic chemicals to be used in the absence of chemical-specific data.

6. Adoption of Water Quality Standards Consistent With the Proposed Guidance

The Great Lakes Guidance for deriving BAFs is included in appendix B of part 132. Examples of BAFs derived using this methodology are also set forth in appendix B of part 132 of the proposed Guidance. The Great Lakes Water Quality Initiative Bioaccumulation Factor Technical Support Document, which discusses the basis for the proposed methodology and which sets forth the data and considerations upon which the individual BAFs are based, is available in the administrative record for this rulemaking. Copies are also available upon written request to the person listed in section XIII of this preamble.

Section 132.4 of the proposed Guidance requires that States and Tribes adopt requirements into their water quality standards that are consistent with the BAF methodology in appendix B of part 132. The State or Tribal regulations need not duplicate the methodology in the proposed Guidance verbatim, but, when presented with a given data base, the methodology adopted by the State or Tribe will be expected to demonstrate to EPA's

satisfaction that the same BAF will be produced as would be produced using the final methodology in the Great Lakes Guidance. To the extent that current State or Tribal regulations or statutes already contain a BAF methodology which is at least as stringent as the final Guidance, the State or Tribe need not reproduce that guidance separately for the Great Lakes basin.

The States and Tribes may adopt a methodology which results in more stringent (higher) BAFs than those which result from the final Great Lakes Guidance; however, this more stringent methodology shall not be offset by less stringent, or compensating, adjustments in the derivation of the wildlife or human health criteria, or in the implementation procedures for those criteria.

7. Literature Cited

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V. Human Health

A. Introduction

The proposed Great Lakes Water Quality Guidance for human health is described below. As with the Guidance for aquatic life discussed earlier, EPA is proposing a two-tier approach for human health. Minimum data requirements for Tier I criteria and Tier II values are discussed later in this section. The proposed Great Lakes Water Quality Guidance is compared below with existing National Guidance for developing human health criteria, and the differences are discussed.

Sample human health criteria have been calculated using the proposed methodology for 20 chemicals. The 20 chemicals chosen for criteria development were selected from the Great Lakes Water Quality Initiative (GLWQI) group of chemicals of concern listed in proposed 40 CFR part 132, Table 6, to represent a broad cross section of the types of chemicals found in the Great Lakes basin. They include: Halogenated and non-halogenated chemicals; bioaccumulative and nonbioaccumulative chemicals; and organic and inorganic compounds. The intent of the chemical selection was to test the proposed methodology against a broad range of chemicals and to demonstrate how the criteria development process will be carried out. Chemical selection from among the chemicals of concern was not made on the basis of health risk priorities, but more from the perspective of demonstrating the proposed methodologies' applicability to all types of chemicals.

Once the proposed methodologies have been finalized, EPA may in the future propose additional Tier I criteria and Tier II values for the GLWQI chemicals of concern or for other pollutants of concern on a health priority basis (see section II.D.2 of this preamble). In addition, microbial agents which are of concern in the Great Lakes may be the focus of future criteria development as well. Developing criteria for microbial agents will require the development of a new methodology to assess microbial risks. (The methodologies presented in today's proposal are designed to assess risks from chemical contaminants; adjustments in methodology will be required to assess the risks from microbial pathogens.) Pending such future EPA action, the Great Lakes States and Tribes will be expected to use the final human health methodology to derive Tier I criteria and Tier II values as described in section II.D.2 of the preamble.

Although EPA requests public comment on all aspects of the proposal, issues are raised throughout the following discussion for which EPA specifically invites comments. The proposed human health methodologies for calculation of cancer and noncancer Tier I criteria and Tier II values are included in appendix C to part 132. A Technical Support Documents for Human Health ("Human Health TSD") which further discusses the basis for today's proposal, and Human Health Criteria Documents which provide the data and considerations upon which the 20 proposed sample human health criteria calculations are based, are available in the administrative record for this rulemaking. Copies of these documents are also available upon written request to the addresses listed in section XIII of this preamble. The Human Health TSD contains discussions and rationales for the selection of different exposure assumptions and risk assessment approaches incorporated in the proposed human health methodologies.

Finally, EPA's expectations for determining whether a State's water quality standards are consistent with the Guidance are set forth in section 132.4 and corresponding preamble discussions.

B. Criteria Methodologies

Existing EPA guidelines for the development of human health criteria were established in 1980. These guidelines can be found at 45 FR 79347, dated November 28, 1980 ("1980 National Guidelines"). The objective of the 1980 National Guidelines is:

> * * * to estimate ambient water concentrations which do not represent a significant risk to the public. 45 FR 79347.

This objective is retained in today's proposed Guidance. The Guidance sets forth criteria and methodologies to derive human health criteria which will

not result in zero risk, but will provide a level of protection likely to be without appreciable risk. At some level of upper bound incremental risk, generally between one in ten thousand (10^{-4}) and one in one million (10^{-6}), the incremental risk of developing cancer may be deemed sufficiently small not to be appreciable.

1. Endpoints Addressed by the Human Health Methodologies

The 1980 National Guidelines recognize the need for ambient water quality criteria based on three types of biological effects or endpoints: Carcinogenicity, toxicity (i.e., all adverse health effects other than cancer) and organoleptic effects (taste and odor). The proposed Guidance addresses only the first two of these types of effects. The Committees of the Initiative felt that organoleptic effects, while significant from an aesthetic standpoint, were not a significant health concern and, given competing priorities, did not warrant inclusion in the proposed Guidance at this time. While it can be argued that organoleptic properties indirectly affect health, (people may drink less water or eat less fish due to objectionable taste and odor), they have not been demonstrated to result in direct human health effects such as cancer or other toxicity. In any event, the current National criteria guidance developed for organoleptic effects will continue to be available for use by Great Lakes States and Tribes in developing criteria, as before.

As one possible alternative to today's proposal, EPA invites comment on whether EPA should require the Great Lakes States and Tribes to adopt Tier I criteria identical to the existing National guidance for organoleptic substances developed under section 304(a) of the Clean Water Act. There are 13 chemicals and/or chemical classes for which National organoleptic-based criteria exist (45 FR 79355). They are: Acenaphthene (20 µg/L), monochlorobenzene (20 µg/L), chlorophenols (0.1 µg/L), dichlorophenols (.04–.5 µg/L), trichlorophenols (1–2 µg/L), tetrachlorophenols (1 µg/L), methyl chlorophenols (20–3000 µg/L), pentachlorophenol (30 µg/L), phenol (0.3 µg/L), nitrobenzene (30 µg/L), hexachlorocyclopentadiene (1 µg/L), copper (1 mg/L) and zinc (5 mg/L). EPA also requests comments on whether these numeric organoleptic criteria should be updated if incorporated in the final Great Lakes Water Quality Guidance to reflect new data or a different methodology. Finally, EPA request comments on whether organoleptic criteria for other chemicals should be developed and on the priority EPA should assign to such efforts in comparison to derivation of Tier I criteria and values for other pollutants on Table 6 of 40 CFR part 132.

The 1980 National Guidelines define adverse effects as "any effects which result in functional impairment and/or pathological lesions which may affect the performance of the whole organism, or which reduce an organism's ability to respond to an additional challenge (45 FR 79353). The Great Lakes Guidance proposed today is intended to similarly protect humans from adverse effects, as defined by the 1980 National Guidelines, and has attempted to identify all possible adverse effects by broadly defining adverse effects as acute, subchronic and chronic toxicity including reproductive and developmental effects.

2. Mechanism of Action: Cancer and Noncancer

a. *Cancer.* Under the 1980 National Guidelines, carcinogenicity is regarded as a non-threshold phenomenon. Under that assumption, "no effect" levels for carcinogens (other than zero) cannot be established, because even extremely small doses are assumed to potentially elicit a finite increase in the incidence of cancer. EPA calculates numeric criteria corresponding to various upper bound incremental risks of developing cancer (e.g., concentration X is associated with an estimated upper-bound increased risk of developing cancer over a lifetime of exposure of 1 cancer per 100,000 individuals exposed). Typically, upper bound incremental risks of developing cancer between one in ten thousand (10^{-4}) and one in one million (10^{-6}) are deemed sufficiently small to not be appreciable. This is supported by the discussion of everyday risks presented in Table I of the Human Health TSD. Recognizing the primary role accorded to States under the Clean Water Act to develop protective water quality standards, EPA has historically given States considerable latitude to determine the precise level of incremental cancer risk that they consider to represent no appreciable risk.

Research conducted by a variety of individuals in the mid-1980s (see Human Health TSD—Section III B—for a detailed discussion of the mechanisms of carcinogenicity) suggests that the process by which a chemical causes cancer is based upon at least two stages: Initiation and promotion. According to this research, individual chemicals may be initiators, promoters, or both. Chemicals which display both characteristics are termed "complete carcinogens." Those chemicals that are capable of triggering the carcinogenic process by a variety of genotoxic mechanisms are termed "initiators." These chemicals are capable of directly altering DNA in an irreversible manner.

Other chemicals may not act on DNA, but nevertheless alter the expression of the initial genome and/or enhance tumor development by nongenetic mechanisms. These chemicals are termed "promoters." Their effects may be reversible and dose-dependent and may require prolonged or repeated exposure. This type of cause and effect relationship indicates that a threshold dose may exist below which the expression (promotion) of an initiated gene may not occur (i.e., develop a tumor).

Currently, data are not available to determine the exact mechanism by which most chemicals cause cancer. As a result, significant controversy exists regarding the existence of "safe" threshold doses for carcinogens. Today's proposed Guidance would require that a non-threshold mechanism should be assumed for carcinogens unless data exist that demonstrate a threshold mechanism. This is generally a conservative assumption which results in more stringent criteria, and thus offers greater protection. However, recognizing the recent advances in the understanding of chemical carcinogenesis, the proposed Guidance departs from the 1980 National Guidelines, but follows the 1986 EPA Guidelines for Carcinogen Risk Assessment (51 FR 33992 (September 24, 1986)), by allowing for use of a threshold assumption in deriving criteria when data sufficiently support that assumption for a particular carcinogen. A sufficient demonstration of a threshold is made on a case-by-case basis, weighing all the studies for a particular chemical to determine whether a true threshold effect is occurring across all sensitive test species. It is recommended that States and Tribes confer closely with EPA prior to submitting for EPA approval/disapproval any criterion for a carcinogen that is based on the assumption that a "safe" threshold dose exists for the chemical.

b. *Noncancer.* Noncancer endpoints of toxicity are assumed to exhibit a threshold. This means there is a dose below which no adverse effects should be observed, or if an adverse effect is observed, the risk of deleterious effect over the span of a lifetime is not appreciable. See, e.g., 1980 National Guidelines. However, there are some exceptions to this principle: For some

non-carcinogenic effects, no identifiable threshold has been demonstrated. Chemicals which may exert non-threshold non-cancer effects include genotoxic teratogens and germline mutagens. EPA has recognized this potential in its "Proposed Amendments to Agency Guidelines for Health Assessment of Suspect Developmental Toxicants" (Proposed Amendments to Agency Guidelines for Health Assessments of Suspect Developmental Toxicants, 56 FR 63798, (December 5, 1991)) and in the Guidelines for Mutagenicity Risk Assessment (Guidelines for Mutagenicity Assessments, 51 FR 34007, (September 24, 1986)). Today's proposed Guidance would require that a threshold mechanism of action be assumed in deriving criteria for protection against noncancer effects, unless it is demonstrated on a case-by-case basis that there is no threshold with respect to a given chemical's toxicity effect(s). Therefore, while today's proposed Guidance goes beyond the 1980 National Guidelines by acknowledging that noncancer effects may not demonstrate a threshold, it is consistent with the latest revision of the guidelines for developmental and mutagenic risk assessments.

In the rare instance that this type of chemical is encountered, it is recommended that States and Tribes confer closely with EPA prior to establishing a noncancer criterion on the basis of a non-threshold effect.

3. Choice of Risk Level

Human health water quality criteria for cancer-causing substances are typically expressed in concentrations associated with a plausible upper bound level of increased risk of developing cancer. EPA derives criteria using a cancer potency factor which is an upper 95th percentile confidence limit of the probability of response based on human or experimental animal data. This plausible upper bound estimate means EPA is reasonably confident that the "true risk" will not exceed the risk estimate derived by this model, may be less than predicted, and could be as low as zero.

In practice, the plausible upper bound cancer risk generally accepted by States, Tribes and EPA for exposure to individual chemicals present in surface waters typically ranges between one in ten thousand (10^{-4}) and one in a million (10^{-6}). Under the Guidance proposed today, the criteria derived correspond to a plausible upper bound increased risk of developing cancer of 1 in 100,000 (10^{-5}) over a lifetime of exposure. The choice of risk level was based on the best professional judgment of the Technical Work Group and is within a range that EPA has historically used in EPA actions, and approved for State and Tribal actions. The majority of the Great Lakes States traditionally have used a 10^{-5} risk level in setting their water quality criteria.

EPA invites comment on this choice of risk level, and on alternate risk levels, such as 10^{-6} and 10^{-4} which could be adopted in the final Great Lakes human health criteria methodology. Decreasing the risk level by a factor of 10 (i.e., from 10^{-5} to 10^{-6}) results in a corresponding 10-fold decrease in numeric criteria and values (e.g., from 10 µg/L to 1 µg/L), while increasing the risk level by a factor of 10 (i.e., from 10^{-5} to 10^{-4}) results in a corresponding 10-fold increase in criteria and values. Consistent with the 1980 National Guidelines, under today's proposal, criteria for protection against non-cancer effects are derived so as to prevent hypothetically exposed individuals (i.e., those consuming pollutant-bearing fish and drinking water at the rate assumed in the criteria-derivation formulas explained below) from receiving a dose of the chemical above that which is calculated to correspond to no appreciable risk of adverse effect, based on a threshold model of chemical activity.

4. Acceptable Dose

Today's proposal and the 1980 National Guidelines are based on the principle that the potential for a chemical to cause an adverse effect (e.g., carcinogenicity, toxicity) depends on: Dose; the amount of the chemical needed to induce the adverse effect; and duration of exposure. Under today's proposed Guidance, the dose associated with a one in one hundred thousand plausible upper bound risk of developing cancer from lifetime exposure to a carcinogen is called the Risk Associated Dose (RAD). The dose of a noncarcinogen expected to result in no appreciable risk of adverse health effects upon lifetime exposure is referred to as the Acceptable Daily Exposure (ADE).

a. *RAD.* Determining a Risk Associated Dose (RAD) under today's proposed Guidance will typically involve the following steps: Establishing through review of scientific studies on humans and/or animals that enough evidence exists regarding the potential of the chemical to cause cancer to warrant treating it as a known, probable or possible human carcinogen for purposes of criteria derivation; using available data (typically from animal studies) to establish a relationship between the dose of the chemical administered and carcinogenic response; translating a dose/response relationship based on animal data into an assessment of risk to humans; and calculating the specific dose to humans that will correspond to the particular risk level of interest (in this case, the 10^{-5} risk level). It is important to note that many of these steps may have already been conducted by EPA for a particular chemical and the results made available to the public through EPA's Integrated Risk Information System (IRIS). It is recommended that IRIS be consulted when developing a RAD.

The first step in developing a RAD involves determining whether scientific evidence supports treating the chemical as a human carcinogen for purposes of criteria derivation. The considerations to weigh in making this determination are described in section II.A of the proposed methodology and the Human Health TSD and can also be found in the 1986 EPA Guidelines for Carcinogen Risk Assessment (51 FR 33992).

The second step in deriving a RAD involves using scientific studies that correlate varying doses of a chemical with carcinogenic response ("dose response studies") to establish a dose response relationship for the organism exposed in the study that will allow estimation of carcinogenic response at doses other than those actually administered in the study. Typically, insufficient data are available from epidemiological studies to form the basis for derivation of a dose response relationship suitable for criteria development. Where such epidemiologic data are available, however, today's proposed Guidance specify that they should be used to calculate a criterion. In the usual situation where epidemiological studies are insufficient for this purpose, the Guidance provides for the use of animal data. When animal studies are used to estimate effects on humans, data from species most biologically relevant to humans are generally preferred (i.e., a species in which pharmacokinetics and/or toxic mechanisms of action appear closely related to humans. For example, it is generally accepted that results from rodents are more likely to be relevant than results from birds). In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species exhibiting a carcinogenic response at the lowest administered dose (given a relevant route of exposure), should be used.

Typically, dose response tests are conducted at relatively high doses of the

chemical of concern. The purpose of such an assay design is to ensure that an effect will be seen, if one is to occur, during the timeframe of the study. As a practical matter, it is generally not feasible to conduct a valid laboratory test to measure the dose that will actually yield only one cancer among a hundred thousand test organisms, even though it is that level of response that would be most relevant for purposes of deriving criteria pursuant to today's proposed Guidance. Accordingly, the information available on cancer response in test organisms exposed to high doses of a chemical is used to estimate the level of cancer response that would likely occur if doses were substantially reduced. Various models have been developed to perform this extrapolation, based in part on various theories of how chemicals operate to produce cancer. Consistent with EPA's general assumption, discussed above, that carcinogens act in a non-threshold manner, EPA is proposing that a Linearized Multistage Model ("LMS") be used to extrapolate from actual animal bioassay data to the dose/response relationship expected at low doses, unless it can be established on a case-by-case basis that another model is more appropriate. EPA uses Global '86 to determine cancer potencies. Global '86 is a revised LMS derived by Howe, Crump, and Van Landingham (1986). (Howe, R., K. Crump, and C. Van Landingham, Computer Program to Extrapolate Quantitative Animal Toxicity Data to Low Doses. Prepared for EPA under subcontract #2–251U–2745 to Research Triangle Institute.) Use of the LMS for this purpose is consistent with the 1980 National Guidelines. A LMS yields a very protective estimate of potential cancer response at low doses because it is based on a non-threshold assumption of carcinogenicity. EPA estimates risks using the 95 percent upper confidence limit on the risk associated with the low extrapolated doses, thereby deriving a "plausible upper-bound" estimate of risk associated with any dose. The model assumes a linear relationship between dose and effect, allowing derivation of a "slope factor" or "potency factor" representing the incremental risk associated with every additional unit of dose expressed in milligrams of the chemical per kilogram of body weight per day.

EPA believes the scientific basis supporting the LMS is better than for other current mathematical extrapolation models, and for this reason it has been adopted as the primary basis for risk extrapolation to low levels of the dose response relationship. As the 1986 EPA Guidelines for Carcinogenic Risk Assessment state:

> When data and information are limited, and when much uncertainty exists regarding the mechanism of carcinogenic action, models or procedures which incorporate low dose linearity are preferred when compatible with the limited information. At present, mechanisms of the carcinogenesis process are largely unknown and data are generally limited. If a carcinogenic agent acts by accelerating the same carcinogenic process that leads to the background occurrence of cancer, the added effect of the carcinogen at low doses is expected to be virtually linear (Crump et al., 1976). In the absence of adequate information to the contrary, the 1986 Guidelines for Carcinogenic Risk provide that linearized multistage procedure will be employed.

Under today's proposed Guidance, other models, such as the "time-to-tumor" model or ones based on modifications of the LMS model, may be used on a case-by-case basis if the data are more appropriately considered by that model. For example, in some studies there are low survival rates of tested animals due to disease or laboratory-related stress. Modifications to the LMS model can account for poor survivability and still allow for a calculation of cancer potency factor based on tumor occurrence in the surviving test animals and the predicted cancer rate of the population that did not survive.

One of the difficulties sometimes encountered in this aspect of criteria development is that the animal study being used to derive a dose/response relationship was not of sufficient duration (due to premature death of test organisms) to measure cancer development over the natural lifespan of the species. In this circumstance, the proposed Guidance requires that the potency factor be adjusted to account for potentially unobserved tumors due to the short study duration. As explained more fully in the 1980 National Guidelines (45 FR 79352) and the Human Health TSD (section III–B), the rationale for this requirement is that the rate of the tumor incidence increases with age, given constant exposure. A short-term study is thus likely to underestimate carcinogenic potential. EPA has developed a factor $(L/Le)^3$, where L is the natural lifespan of the test species and Le is the duration of the study, which will adjust for less than lifetime duration studies. Use of this specific factor is required for use with today's proposed methodology. The slope factor adjustment will be conducted for mice and rat data if the study duration (Le) is less than 78 weeks for mice or 90 weeks for rats, by multiplying the slope factor by the factor $(L/Le)^3$. EPA requests comment on whether the use of this adjustment factor for studies with less than lifetime duration is appropriate.

The third step in deriving a RAD is to translate the dose/response relationship derived for a test organism into an estimated dose response relationship for humans. In today's proposed Guidance, as in the 1980 National Guidelines, it is assumed that a dose expressed as milligrams per unit of body surface area per day will yield equivalent cancer responses in test animals and humans. Thus a "surface area species scaling factor" is proposed for use in deriving a dose response relationship for humans that is based on animal data. EPA uses the surface area scaling factor based on evidence that among different mammalian species many physiological rates, especially ventilation, basal metabolic, and clearance rates tend to scale in proportion to surface area. It has also been found to hold for the acute therapeutic effects of anticancer agents.

Where experimental doses are described in terms of dose per surface area, the surface area scaling factor is easily determined by comparing the surface area of the test organisms with that of the average human. However, scientists typically express doses applied in laboratory tests in terms of milligrams of chemical per unit of body weight of the test organism per day. Since, to a close approximation, the surface area is proportional to the two-thirds power of the body weight (as would be the case for a perfect sphere), exposures in milligrams per kilogram of body weight per day raised to the $^2/_3$ power would also be considered as yielding equivalent cancer responses in test animals and humans under today's proposal. This approach is consistent with the 1980 National Guidelines. Certain researchers, including Travis and White (1988) (see the Human Health TSD), have determined that a three-fourths exponent may be more appropriate, based on a reassessment of historical data on anticancer drugs. EPA specifically requests comment on the proposed use of a two-thirds exponent, and the possible use of a three-fourths exponent, for performing the above-described calculations.

Not all Federal agencies use a surface area species scaling factor to translate a dose/response estimate for test organisms into an assessment of risk to humans. The U.S. Food and Drug Administration (FDA), for example, has traditionally assumed that equivalent doses expressed as milligrams per unit of body weight will yield equivalent

cancer responses (a "body weight species scaling factor"). Scientists differ on whether a body weight or surface area species scaling factor is most appropriate. Some scientists believe a surface area scaling factor fits the data best for drugs and chemicals in which metabolic effects are key to the mechanism of action, such as anticancer drugs. Other studies support views that body weight scaling may be more appropriate for other types of chemicals. As a practical matter, the surface area scaling factor will generally result in a more stringent potency factor than the body weight scaling factor.

An inter-agency work group (Inter-Agency Pharmacokinetics Group) comprised of EPA, FDA, and the Consumer Product Safety Commission (CPSC) has been working on the issue of appropriate, consistent scaling factors for use by all of the agencies in developing risk assessments (57 FR 24152 (June 5, 1992)). If the work group completes its work prior to publication of the final Great Lakes Guidance, and if it determines that a species scaling factor other than the surface area or body weight scaling factors discussed above should be used, EPA will reopen the public comment period to allow comment on possible use of the work group's proposal in the final Great Lakes Guidance. In any event, however, EPA seeks comment on whether use of a body weight, surface area, or some other scaling factor should be used in the final Great Lakes Guidance.

After the above steps have been used to calculate a cancer potency factor for humans, the final step in calculating a RAD is to use the cancer potency factor to calculate a dose in milligrams per kilograms per day that corresponds to a plausible upper-bound incremental cancer risk of one in one hundred thousand. This is the risk associated dose or RAD.

b. *ADE.* For non-carcinogens, today's proposed Guidance establishes a data hierarchy for calculating the Acceptable Daily Exposure (ADE). This process is the same one used by EPA's reference dose (RfD) development process but differs in the amount of data required to develop a number. In some cases, an ADE may be identical to an EPA RfD if the same data and judgments are used. However, these values may differ for reasons explained later in this section, and so to distinguish the two terms from each other, a different term (ADE), defined slightly differently, is being used in the proposed Great Lakes Guidance. EPA defines an RfD as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without appreciable risk of deleterious effects during a lifetime." U.S. EPA 1992, "Reference Dose: Description and Use in Health Risk Assessments." IRIS. Online: Intra Agency Reference Dose Work Group, Office of Health and Environmental Assessment, ECAO, Cincinnati, Ohio. This definition was used as the basis for defining an ADE. In today's proposal, ADE has similarly been defined as an estimate of the maximum daily dose of a substance which is not expected to result in adverse effects to the general human population, including sensitive subgroups.

Calculating an ADE for a chemical involves the following steps: Determining whether there is evidence from epidemiologic or animal studies that exposure to a chemical may result in adverse noncancer health effects; using available data to determine a threshold dose value that is likely to be without appreciable risk of adverse effect; and reducing this threshold dose value to account for uncertainties inherent in the risk assessment to yield an acceptable daily exposure for humans. Many noncancer effects are clearly deleterious to human health, and therefore clearly warrant derivation of water quality criteria to protect exposed populations from them. Such effects include reproductive impairment, developmental toxicity, impaired organ function, reduced body and organ weights, immunotoxicity, etc. For a detailed discussion of what constitutes an adverse effect, refer to U.S. EPA 1992, "Reference Dose: Description and Use in Health Risk Assessments." IRIS. Online: Intra Agency Reference Dose Work Group, Office of Health and Environmental Assessment, ECAO, Cincinnati, Ohio. There are some instances, however, where changes at the cellular or subcellular level may be observed in test organisms, but it is unclear whether these changes are harmful. (For example, minor increases in enzyme activity, may or may not be precursors to or indicators of actual organ damage. These types of effects need to be further validated by histopathological analysis to determine if actual organ damage has occurred.) Today's proposal provides for noncancer criteria that are protective from adverse acute, subchronic and chronic effects including reproductive and developmental effects (see appendix C to part 132, section I.B). EPA believes that the proposed text will allow States and Tribes to consider on a case-by-case basis whether effects other than those cited in the appendix C to part 132, section I.B, i.e., reproductive and developmental toxicity, including observed biological changes not demonstrably linked to adverse effects, should be considered "adverse" for purposes of criteria development. EPA solicits comment on whether it should specify in the methodology a longer list of deleterious effects that noncancer criteria should protect against, and whether the methodology should specifically address criteria development based on observed biological changes not demonstrably linked to an adverse effect.

Once it is determined that exposure to a chemical may result in an adverse effect in humans, available data are used to establish a dose/response relationship. Use of well-conducted human studies (studies which are well designed, peer-reviewed and which provide a basis for causal inference) are favored over use of animal studies for this purpose. When animal studies are used to estimate effects on humans, data from species most biologically relevant to humans are generally preferred (i.e., a species in which pharmacokinetics and/or toxic mechanisms of action appear closely related to humans). If it is not possible to distinguish the animal species that is most biologically relevant to humans, then data from the most sensitive animal species are generally to be used. (The Human Health TSD, section II, provides recommendations on relevant test species for different test endpoints such as cancer, noncancer effects, reproductive effects, etc.) EPA requests comments on the described approach and, particularly, on whether the most sensitive animal species should be used as a default when the most biologically relevant species is not identified or whether another approach should be used.

From these animal data, the experimental exposure level representing the highest dose at which there were no observed adverse effects (the NOAEL) is used for calculating the ADE. If a NOAEL has not been experimentally determined, the dose associated with a lowest observed adverse effect (LOAEL) involving relatively mild and reversible effects (as compared to effects at higher doses) may be used in the case of chronic studies (one year or longer in rodents, and 50 percent or more of the lifespan in other appropriate test species) for ADE derivation. This does not preclude the use of a LOAEL from a study with only one or two doses if the effects appear minimal when compared to effect levels observed at higher doses in other studies. For example, there are many

studies for which only one dose has been tested with resulting minimal, reversible effects such as minimal enzyme changes or body weight decreases. These minimal changes or effects, on their own, may not be thought of as adverse but may be indicators or precursors to more severe effects which result from extended exposure and/or higher doses. In those cases, while it can be argued that such an effect may be a LOAEL, it may also be very close to the NOAEL.

Having established a NOAEL or LOAEL in either an animal or epidemiologic study, the final step in deriving the ADE is to reduce the NOAEL or LOAEL to account for uncertainties in predicting acceptable exposure levels for the general human population. The use of "uncertainty factors" for this purpose is common practice by EPA in deriving noncancer criteria. The size of the uncertainty factor varies depending on the data available for ADE calculation, including whether the data are from a study on humans or test animals, and on whether the study demonstrates a NOAEL or a LOAEL. The 1980 National Guidelines establish three general provisions for deriving uncertainty factors:

i. Valid experimental results from studies on prolonged ingestion by humans, with no indication of carcinogenicity. Uncertainty factor=10.

ii. Valid results of experimental studies of human ingestion are not available. Valid experimental results of long-term feeding studies on animals, or valid animal studies on one or more species. No indication of carcinogenicity. Uncertainty factor=100.

iii. No long-term or acute human data. Scanty results on experimental animals with no indication of carcinogenicity. Uncertainty factor=1000.

Since the 1980 National Guidelines were published, additional research and continuing EPA deliberations have occurred regarding use of uncertainty factors (see, e.g., U.S. EPA, 1992, IRIS; Dourson and Stara, 1983; Regulatory History and Experiment Support of Uncertainty (Safety) Factors, Regulatory Toxicology and Pharmacology. 3:224–238). The three provisions taken from the 1980 National Guidelines apply to just three situations. In developing RfDs, two additional uncertainty factors are now applied to account for conditions such as severity of effect when a LOAEL is used instead of a NOAEL and incompleteness of data set. All uncertainty factors are judged on a case-by-case basis depending on the overall data base. The default value of these factors is 10, but other values have been used (generally 3) and multiple factors are often combined when 4 or 5 are used together.

The most up-to-date EPA guidance on the application of uncertainty factors has been used as the basis of today's proposal (U.S. EPA, 1992, IRIS). For a more complete discussion of the uncertainty factors chosen under various data schemes, refer to appendix A of the Human Health TSD.

Under today's proposal a composite uncertainty factor of 30,000 is the maximum uncertainty allowed when deriving a Tier I criterion or Tier II value. When deriving a Tier I criterion the likely maximum composite uncertainty factor applied to a 90 day NOAEL may be 3000. The total 3000 is based on four separate uncertainty factors: A factor of generally 10 to account for intraspecies variability (the sensitivity within the human population); a factor of generally 10 to account for interspecies variability (intended to account for the uncertainty in extrapolating animal data to the case of humans); a factor combined of generally 30 to account for both subchronic to chronic variability; and to account for an incomplete database (i.e., lack of a reproductive, bioassay, developmental toxicity studies data in two species and a second species general toxicity bioassay). Note here that in the use of these latter two factors, two areas of uncertainty which generally warrant a default value of 10 each have been combined to yield a 30-fold factor.

Under Tier II, the likely maximum composite uncertainty factor may be 30,000 which would be applied to a greater than 28 days minimal LOAEL (e.g., 30 day). The total of 30,000 is based on EPA's standard uncertainty factors (four factors of generally 10 each are used to account for intraspecies variability, interspecies variability, subchronic to chronic variability, and incompleteness of data set) which together warrant the use of a 10,000-fold factor, and an additional factor of 3 to account for the uncertainty in extrapolating from a study greater than 28 days but sufficiently less than 90 days to warrant a factor of 3.

The choice of appropriate uncertainty and modifying factors reflects a case-by-case judgment by experts and should account for each of the applicable areas of uncertainty (described above) and any nuances in the available data that might change the magnitude of any factor. Several reports describe the underlying basis of uncertainty factors (Zielhuis et al., 1979; Dourson and Stara, 1983) and research into this area (Calabrese, 1985; Hattis et al., 1987; Hattis and Lewis, 1992; Hartley and Ohanian, 1988; Lewis et al., 1990; Dourson et al., 1992; Dourson, 1993; Renwick, 1991; 1993).

The use of such uncertainty factors and their application has not been without controversy in the literature. For example, Lewis, S.C., J.R. Lynch and I. Nikiferov, (Regulatory Toxicology and Pharmacology, 11, pp. 314–330, (1990), note that it seems excessive to require a 10-fold uncertainty factor to correct for intraspecies variability, whereas a reading of Calabrese (1985) would suggest that perhaps more than a 10-fold factor is needed. Building on earlier work of Weil (1972) and Dourson and Stara (1983), Lewis et al (1990) suggest that based on 450 studies of lethal doses, for 85 percent of the studied chemicals a factor of 6 was adequate to protect 99.9 percent of the individuals. Lewis et al. (1990) state that lower values for intraspecies adjustments are surely adequate for this 85 percent of chemicals; for another 15 percent, however, a factor larger than 6 is needed.

Lewis et al. (1990) also note that according to some data, a factor of 10 to extrapolate from subchronic effects to chronic effects is excessive. In particular, they write that studies of 41 different chemical agents indicate that a ratio of 3 would be adequate to extrapolate subchronic statistics to estimate corresponding values for chronic exposures in all instances. This point is similar with a careful reading of Dourson and Stara (1983). Citing an earlier series of toxicity experiments, Dourson and Stara state that the ratio of the subchronic to chronic NOAEL or LOAEL "for more than half of the observed chemicals are 2.0 or less". This result indicates that the chronic NOAEL or LOAEL was 2-fold less than the corresponding NOAEL or LOAEL for more than half of the given chemicals after subchronic exposure. Further, Dourson and Stara write "approximately 96 percent of these ratios are below a value of 10." Thus the empirical evidence on differences between chronic and subchronic exposure effects on laboratory animals would suggest that use of a default uncertainty factor of 10 in the absence of chemical-specific data should be regarded as a loose upper bound to the range of values associated with these ratios. These factors of 10 are not average values.

EPA defines the RfD as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." U.S. EPA 1992, Reference Dose: Description and Use in Health Risk

Assessments. IRIS. Online: Intra Agency Reference Dose Work Group. Office of Health and Environmental Assessment, ECAO, Cincinnati, Ohio. Given this definition, it has been EPA's practice to use default uncertainty factors of 10 that are loose upper bounds to the potential range of values. Nevertheless, EPA solicits comments on the uncertainty factors included in this proposal, and particularly on whether other uncertainty factors might offer better assessment of risk, and be more appropriate in deriving water quality values and criteria.

c. *IRIS.* EPA currently has a process to develop consensus on cancer slope factors and RfDs (referred to as ADEs for the Great Lakes). These values are derived by two EPA work groups, called the RfD/RfC and CRAVE work groups, and made available as guidance to EPA program offices and to the public via a database called the Integrated Risk Information System (IRIS). The IRIS values (RfDs and cancer slope factors) are recommended for use as a starting point by various EPA programs for the development of regulations and guidance.

Today's proposed Guidance recommends that the IRIS cancer slope factors and RfDs (ADEs) be considered as a first step in deriving the Great Lakes Human Health criteria. In certain circumstances, however, deviation from these values can be expected. First, the Great Lakes cancer slope factors and ADEs may differ where they are based on new data that were not available at the time EPA work groups derived the IRIS values. This will ensure that the criteria are derived based on the best available information.

For example, the mercury value presented in today's proposal is based, in part, upon data that was not considered by EPA's RfD work group. The ADE for mercury used to calculate today's proposed Tier I HNV is, therefore, different from the RfD which currently appears in IRIS. Although this type of discrepancy could likely be remedied by updating IRIS values at the same time that Great Lakes criteria and values are derived, this will not always be possible given the heavy workload of the IRIS work groups.

Second, EPA work groups may not have followed the procedures specified in today's Guidance in deriving their values, or they may have interpreted the data differently. Where detailed risk assessment methodology guidance is lacking, case-by-case decisions based on professional judgement may differ. In today's proposal, when an ADE or RAD differs from the values in IRIS, the Great Lakes Technical Work Group may have interpreted the science slightly differently than the RfD or CRAVE work group for a particular chemical. Scientific justification supporting such deviations from IRIS guidance is provided in the individual Tier I criteria technical support documents included in the administrative record to today's proposal. For example, today's RAD for dioxin is based on a cancer slope factor which differs from the IRIS cancer slope factor for dioxin. While both cancer slope factors are derived using data from the same rat feeding study, different pathologists reviewing the slides from that study have counted the tumors differently, and therefore have come to somewhat different conclusions regarding the potential of the chemical to cause cancer. The IRIS slope factor is based on a tumor count conducted in 1978, while the slope factor used to derive today's proposed criteria is based on a tumor count of the same slides that was conducted in 1990, using a somewhat different protocol for counting tumors. This issue is described more fully in the human health criteria document for dioxin which is available in the administrative record for today's rulemaking. EPA's CRAVE work group has not yet considered whether to change the IRIS dioxin cancer slope factor based on this new information. This and other new scientific information is currently undergoing extensive review by EPA's Office of Research and Development as part of a comprehensive reassessment of dioxin toxicity, discussed in more detail below.

Third, in some cases, EPA work groups may not have developed RfDs or cancer slope factors for some chemicals, or previously calculated values have been withdrawn from IRIS. The methodology proposed today may be used to develop cancer slope factors and ADEs for the purpose of setting human health criteria in the absence of IRIS values for a particular chemical.

EPA requests comments on deviating from IRIS values in deriving Great Lakes criteria and values for the reasons highlighted above.

5. Exposure Assumptions

Today's proposed Guidance identifies seven factors which affect an individual's oral exposure to a chemical. These are: Body weight; duration of exposure; recreational exposure; drinking water consumption; fish consumption; bioaccumulation factor and relative source contribution.

a. *Body Weight.* Today's proposed criteria methodology, as well as existing National criteria methodology, assume a mean adult human body weight of 70 kg. This value is consistent with that recommended in the EPA's Exposure Factors Handbook (EPA 600/8–89/043, July 1989), which is available in the administrative record for this rulemaking. Data in the handbook indicate that the mean body weight of adults is 71.8 kg on a National basis which can be rounded to 70 kg. While there is some evidence based on regional data isolated from the National Health and Nutritional Examination Survey (NHANES II) that mean weight may be slightly higher than 71.8 kg within the Great Lakes basin, this data can also be rounded down to the 70 kg value. Use of a slightly lower body weight value will result in a slightly more stringent criteria; EPA views a rounding down of body weight data to be a conservative approach. EPA requests comments on the use of the 70 kg body weight assumption and also asks for comments on the issue of using body weights of sensitive subpopulations (such as children) when a chemical's toxicity indicates a specific subpopulation is most sensitive to exposures.

b. *Duration of Exposure.* Today's proposed Guidance assumes that oral exposure remains constant for a lifetime. The exposure values are based on, or consistent with, Great Lakes-specific data. While the exposure assumptions could be over- or under-protective for individuals who live a portion of their lives outside the Great Lakes basin (in areas where their exposures are different), EPA believes that it would not be practical to attempt to derive exposure assumptions that would take into account the movement of people in and out of the Great Lakes basin. EPA believes it is reasonable to derive criteria based on exposures of those individuals living their entire lives in the Great Lakes basin. Since drinking water and fish consumption in the Great Lakes is equal to or greater than that of most other areas of the country, the exposure assumptions should be appropriately conservative for most if not all individuals moving in and out of the Great Lakes area. EPA requests comments on the use of longer lifetime exposure periods, such as 75 years instead of the currently proposed 70 years. EPA also requests comments on whether the use of shorter exposure periods (i.e., less than 70 years) would be more appropriate to account for mobility of individuals in and out of the Great Lakes basin.

c. *Incidental Exposure.* The incidental ingestion exposure factor relates to oral exposures which might occur through recreational activities in or on the water. This factor is relatively small, and has not been included in the derivation of

the existing National criteria. While the contribution from recreational exposures is estimated to be small for the Great Lakes region based on estimates of recreational activity in the Great Lakes basin, EPA believes that including the factor in today's Guidance represents a marginal improvement over the existing National approach. The value proposed (0.01 liter/day) for use in today's Guidance represents oral exposures only, and is based primarily on evaluation of recreational exposure estimates made by EPA in 1979 (U.S. EPA, 1979, Identification and Evaluation of Waterborne Routes of Exposure from Other than Food and Drinking Water. Office of Water Planning and Standards, EPA 440/4–79–016) and on recreational activities data compiled by the State of Michigan. These data are summarized in the Human Health TSD (Exposure Assumptions, section III.D) which describes in detail the basis for today's proposal. EPA also requests comments on whether a factor should be included for incidental dermal exposure which occurs through recreational activities. EPA requests submission of any data that could be used to derive such a factor. Some studies with chemicals, such as trichloroethylene, have shown that dermal uptake occurs in animals exposed to the chemical in water (Bogen, K.T., et al., 1992, Dermal Absorption of Dilute Aqueous Chloroform, Trichloroethylene, and Tetrachloroethylene in Hairless Guinea Pigs, Fundam. Appl. Toxicol., 18:30–39), which is available in the administrative record for this rulemaking.

d. *Drinking Water Consumption.* The current National human health criteria assume a drinking water consumption rate of two liters per day. Originally, this value was adopted from the U.S. Army which has established that figure as the amount needed for military personnel in the field. This number was later adopted by the National Academy of Sciences in developing drinking water risk assessments (NAS, 1977. Drinking Water and Health. p. 11.). EPA has reviewed additional data (several studies in different parts of the country) on drinking water consumption which indicates that the average adult water consumption rate is 1.4 liters per day (USEPA, 1989, Exposure Factors Handbook, EPA/600/8–89/043). However, the data also indicates that two liters per day is a reasonably conservative assumption of at least the 90th percentile consumption value for the Great Lakes basin (Cantor, K.P., et al. 1987. Bladder cancer, drinking water source, and tap water consumption: A case control study. J. National Cancer Institute 79(6):1269–1279). The data from Cantor's study are taken from several mid-west and east coast cities and states, including Detroit and Iowa, which are considered representative of the Great Lakes region. EPA is proposing that the criteria be derived using this 90th percentile ingestion value of two liters per day, but requests comment on whether selection of another value such as 1.4 liters per day would be more appropriate. It should also be noted that, since the two liters value is a conservative assumption (only 10 percent of the population drinks two liters of water a day and considerably less can be expected to drink two liters of untreated surface water) and the 0.01 liter associated with incidental exposure is so minute, EPA presumes that two liters per day is protective of both drinking water and incidental ingestion exposures for waters which may be both a drinking water source and used for recreation. EPA requests comments on whether such an assumption is justified. EPA also requests comments on whether surface water criteria for waters designated for drinking water uses should assume consumption of untreated water, as is proposed.

e. *Fish Consumption.* Today's proposal includes a fish consumption rate of 15 grams per day. This differs from the 6.5 grams per day value which is used in the derivation of the existing National criteria. The 6.5 grams per day value represents a National average consumption value for freshwater and estuarine fish and shellfish, whereas the proposed Great Lakes value represents at least the mean exposure level for regionally caught fish for the regional sportfishing population. (Based on regional population data, including information on the number of sportfishing licenses bought and used, members per family, and measured fish consumption rates, it is predicted that approximately 90% of the entire regional population consumes 15 grams or less of regionally caught fish per day.) Thus, a more conservative target population was chosen than is used in the National criteria methodology and the proposed fish consumption value is based on Great Lakes-specific statistical data. The actual value of 15 grams per day was derived from review of several regional studies in Michigan (West, et al., 1989), Wisconsin (Fiore et al., 1989) and New York (Connelly, et al., 1990). The Human Health TSD (Section D—Exposure Assumptions) provides an analysis of these studies, and discusses the derivation of the 15 grams per day value. While some of the sportfishing population (and other subpopulations such as subsistence anglers) may consume more than 15 grams per day, EPA believes these values are very protective of the entire population for the following reasons:

i. The fish consumption estimate is an estimate of fish carrying the highest body burden of pollutant that will be allowed through implementation of the criteria. Since it is highly unlikely that even those who eat more than 15 grams per day of all freshwater fish will eat more than the equivalent of 15 grams per day of maximum pollutant-bearing fish, the consumption rate will also be protective of the high end consumer.

ii. The proposed Guidance allows for the use of higher fish consumption rates and drinking water rates in developing site-specific criteria (see section VIII.A of this preamble) which would provide increased protection for those particular waters that are heavily used by subpopulations that may not be adequately protected by State-wide criteria, such as certain subsistence anglers.

f. *Bioaccumulation Factor (BAF).* The BAF is the ratio of the pollutant concentrations in aquatic organisms to pollutant concentrations in the waters in which they live. Because some chemicals have a tendency to accumulate in fatty tissues, concentrations of such chemicals in aquatic organisms can be thousands of times greater than in ambient waters. Today's proposal includes a methodology for deriving BAFs, and technical support documents describing the methodology and BAF derivation for those chemicals for which human health and wildlife criteria are proposed. The preamble to the BAF methodology discussed differences between the proposed approach and the existing EPA approach.

g. *Relative Source Contribution.* Under today's proposed Guidance, EPA assumes an 80 percent relative source contribution (RSC) from surface water pathways (water and fish) for bioaccumulative chemicals of concern (BCCs), and 100 percent RSC for non-BCCs, in deriving noncancer criteria/values. A 100 percent RSC is assumed for all chemicals in deriving cancer criteria/values.

The existing 1980 National guidelines assume a 100 percent RSC for all chemicals, unless there are specific data available on other ingestion and inhalation exposures. In practice, when calculating human health criteria, these other exposures (ingestion and inhalation) were generally excluded because accurate data on these other

exposure pathways were not available. However, in a total exposure evaluation, there may be exposures from food, air and soil for a given chemical.

To at least partially account for exposures through other pathways, the Great Lakes Technical Work Group developed a RSC for surface water pathways of 80 percent for bioaccumulative chemicals of concern (BCCs). (See the "definitions" section to determine whether a chemical is considered "bioaccumulative chemical of concern.")

The RSC factor is based upon the concept described in EPA's National Primary Drinking Water Regulations (January 30, 1991, 56 FR 3535) where, in the development of maximum contaminant level goals (MCLGs) for drinking water, a relative source contribution from drinking water is assumed to be 20 percent in the absence of actual exposure data.

For non-BCCs, the Great Lakes Technical Work Group proposed a RSC of 100 percent. The Work Group reasoned that bioaccumulative chemicals are those for which surface water pathways are likely to be major contributors to total human exposure and, therefore those upon which the surface water program should particularly focus in achieving pollutant discharge reductions. For non-bioaccumulative pollutants, assuming less than 100 percent RSC could force large-scale reductions in discharges that are relatively insignificant compared to other exposure routes. The Technical Work Group reasoned that the other more significant routes of human exposure should be addressed through other regulatory efforts, rather than attempting to eliminate relatively insignificant exposures via greater control of discharges to surface waters.

EPA requests comments on today's proposal and on possible alternatives to today's proposal for derivation of noncancer criteria and values, such as: Providing for and/or requiring the use of actual data, when available, to calculate the ambient surface water exposure contribution to the total human exposure for both bioaccumulative and non-bioaccumulative chemicals, in lieu of using the proposed default approach for nonbioaccumulatives only; the use of 100 percent exposure from surface water for all pollutants; the use of a "basement" and "ceiling" ranging from 20–80 percent when actual data indicate the RSC is below 20 percent or greater than 80 percent, the use of alternative default percentages (e.g., 20–40 percent for non-bioaccumulative pollutants and 40–60 percent for bioaccumulative pollutants to ensure greater protection from unknown sources), when intake data from other exposure routes are not available to characterize overall exposure; and the inclusion of a provision allowing flexibility in adjusting a calculated RSC upward or downward depending on how much actual total exposure from all ingestion pathways approaches the health-based RAD or ADE. EPA also requests public comment on whether any of the options described in this preamble for use of an RSC in deriving noncancer criteria and values should be considered in calculating Great Lakes cancer criteria and values (HCVs).

h. *General Considerations.* Although the methodology proposed today provides that *all* adverse effects (including acute and subchronic effects) should be evaluated in deriving an HNV, the methodology utilizes the same set of exposure assumptions regardless of the type of effect chosen as the basis for criteria/value derivation. The exposure assumptions include the 15 gram-per-day fish consumption value and the two liter per day drinking water value described above. These assumptions are based on long-term average consumption rates that are most appropriate for use in deriving criteria protective against long-term chronic effects. It can be expected, for example, that people may eat as much as one-half to one pound (224 to 448 grams) of fish in a single meal, and that there may be occasions (such as on recreational fishing outings) when such large fish meals are consumed on a daily basis for several consecutive days. The two liter drinking water consumption rate may represent a worst-case assumption for most people (see Exposure Factors Handbook); however, there may be subpopulations, such as manual laborers, for whom it is not. The concern from a health standpoint is that a human might receive a large enough dose of a chemical from consuming a large amount of fish or water over a short time period to result in acute or subchronic toxicity.

Accordingly, EPA invites comment on whether the final methodology should specify a different set of exposure assumptions for use in deriving criteria protective of acute and subchronic effects. Data supporting a value other than the two liter per day drinking water consumption estimate is specifically requested. In addition, EPA invites comment on the possible use of 448 grams (one pound) as a reasonable worst-case, one-day fish consumption estimate and 2,240 grams as a reasonable worst-case, 10-day fish consumption estimate (based on 10 consecutive days of consumption of one-half pounds of fish). These values could be used in deriving one-day and 10-day criteria/values protective of acute and subchronic effects. EPA's drinking water program has used these exposure periods in deriving drinking water health advisories. EPA invites comment, however, on whether different exposure periods would be more appropriate in deriving surface water criteria/values. EPA also invites comment on the possibility of requiring the derivation of criteria/values addressing short-term, high level exposures where sufficient data exists, and providing that the more stringent of the chronic criteria/values or the acute/subchronic criteria/values should apply in regulating Clean Water Act discharges.

Finally, EPA also requests comments on the option of changing all exposure levels such as using 1 liter/day for a water consumption factor, a lower fish consumption rate, and a lower duration of exposure level, in order to develop a criterion exclusively developed for a child.

6. Minimum Data Requirements/Tier I and Tier II

In developing today's proposal, the Initiative Committees worked to address a perceived shortcoming associated with the existing 1980 Guidelines' human health water quality criteria methodology. The shortcoming involves the need for a fairly extensive database before a human health criterion can be derived and a discharge permitted. Although a NOAEL from a 90-day study (which is a minimum requirement of the 1980 National Guidelines in order to develop a noncancer criterion) does not appear to represent an extensive database to develop a Tier I criterion, a 90-day study may cost up to $120,0000 to complete and may result in even more cost and time expenditures if histopathology is performed on test animals. In addition, many 90-day studies are preceded by range finding studies which add to overall time/cost expenditures. With regard to Tier I cancer criteria, a long-term or lifetime study (generally a year and a half to two years of exposure) in a rodent is a minimum requirement to determine potential carcinogenicity. This extensive database requirement has resulted in lack of criteria for many chemicals and a resultant case-by-case determination by States in order to permit a particular chemical discharge. In a worst case scenario, it may have resulted in the discharge of a particular chemical without consideration of health effects, thus potentially endangering the welfare of the human population in the area of

the discharge. In other cases, the State has regulated a poorly characterized chemical by using a technology based permit limit or a broad chemical parameter such as chemical oxygen demand (COD) or total organic carbon (TOC).

Generating the required criteria development database can take many months or years and may be very expensive. Further, it may be necessary for States to quickly decide an acceptable ambient level of contaminants. To address this issue, a Tier II methodology, which requires a less extensive database (similar to the Tier II methodology for the development of aquatic life values), is also proposed herein for the development of human health values.

a. *Carcinogens.* The methodology for deriving Tier I criteria and Tier II values for carcinogens (the human cancer values or HCVs) is identical. However, the Tiers are distinguished by weight of evidence, and the amount and quality of data that is required for use in deriving the criteria or values. The goal is to eventually have sufficient data developed on the Tier II chemicals to allow development and adoption of Tier I criteria.

Tier I HCVs are calculated for chemicals for which data exist which are sufficient to classify the chemical as a human carcinogen (Group A under the existing EPA classification scheme described in detail in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (51 FR 33992), or a probable human carcinogen (Group B). In addition, for possible human carcinogens (Group C), for which data may be quantified, a Tier I criterion may be developed when studies have been well-conducted yet are limited because they involve only a single species, strain, or experiment which does not demonstrate a high incidence, unusual site or type of tumor or early onset.

Under today's proposed methodology for Tier II carcinogens; the Group C carcinogen data may be used in developing a Tier II value, where the data are sufficient (i.e., enough data is available to conduct a quantification, yet is still limited based on Tier I requirements, see section II.1 of appendix C to part 132). Readers are referred to the Human Health TSD for a more detailed discussion on the amount of data needed to conduct a quantification.

Chemicals are classified as possible human carcinogens (identified as Group C under the present EPA cancer classification scheme) for many reasons, including the following:

1. Carcinogenicity has been documented in only one test species and/or only one cancer bioassay and the results do not meet the requirements of "sufficient evidence;"

2. Tumor response is of marginal significance due to inadequate design or reporting;

3. Benign but not malignant tumors occur with an agent showing no response in a variety of short-term tests for mutagenicity; and

4. There are responses of marginal statistical significance in a tissue known to have a high or variable background rate.

The chemicals which fall under these four categories of Group C theoretically may be as potent or dangerous to humans as known human carcinogens (identified as Group A under the present EPA cancer classification scheme) or probable human carcinogens (identified as Group B under the present EPA classification scheme) but have not been as well or extensively tested with regard to both human and animal studies. For these reasons, the proposal today requires that Tier I criteria be set for those types of Group C chemicals which are well characterized and supported by a well-conducted study. For those Group C chemicals in which the cancer study (or studies) indicate(s) a significant increase of cancer in test animals but are limited by either: a marginal statistical correlation between chemical and tumors due to high control tumor incidence, a weak dose-response relationship, or an incidence of benign tumors rather than malignant tumors, Tier II cancer values shall be derived. If a cancer quantification cannot be conducted due to lack of data (number of test animals, and or only one dose group of animals has responded, making it impossible to determine a slope factor) then the chemical must be assessed on a noncancer basis and a Tier I or II criteria or value (HNV) should be developed, if available data exists. An option, which EPA requests comments on, is whether a Tier II value could be set for an unquantifiable Group C chemical. For instance, benign tumors or other precursors to malignant tumors such as hyperplastic nodules or peroxisome proliferation could be quantified (in the cases of benign tumors) or used as a sensitive pre-cancer endpoint to set a value.

The proposed Great Lakes Guidance differs from the existing 1980 National Guidelines, in that all possible carcinogens (Group C) are not being treated similarly. The 1980 National Guidelines required the development of criteria based on cancer risk levels of 10^{-5} to 10^{-7} for all Group C carcinogens. Today's proposal is distinguishing Group C carcinogens by the amount of data present and the ability to quantify the cancer risk.

In addition, the Great Lakes proposed Guidance differs from the policies of some parts of EPA with regard to its treatment of Group C chemicals. Under the Safe Drinking Water Act, for Group C contaminants, the Maximum Contaminant Level Goal (MCLG) is usually based on the RfD approach when sufficient non-carcinogenic data are available. An additional one-to-ten fold safety factor is used to account for possible carcinogenicity. The resulting MCLG can then be compared to a MCLG derived using a cancer risk assessment approach if the cancer data are quantifiable. These comparisons are made to ensure that there are no large discrepancies in the numbers derived using both approaches. To date, no large discrepancies have occurred. If adequate data are not available to determine an RfD, then the MCLG is set at the 10^{-5} to 10^{-6} excess cancer risk level where such quantification is appropriate.

EPA under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) examines the risk for Group C contaminants using both an RfD approach and quantification of cancer risk using the cancer potency. When using the RfD method, EPA does not add an extra uncertainty factor to account for possible carcinogenicity in its application of FIFRA. However, EPA does limit the use of the chemical (i.e., cannot be used as a food additive) when derived under the RfD method. Either method may be an appropriate method for risk management decisions.

EPA specifically requests comments on: the procedures proposed today for derivation of Tier I criteria and Tier II values for possible carcinogens ("Group C"); and the alternative of using an additional uncertainty factor (up to 10) on a noncancer endpoint for Group C chemicals to provide protection from possible carcinogenicity (a HNV calculated with an extra UF of 10 to protect against possible carcinogenicity would result in protection from both cancer and noncancer endpoints); and the alternative of deriving criteria and values for Group C only through noncancer assessments without an added uncertainty factor for possible carcinogenicity.

b. *Non-carcinogens.* For non-carcinogens, there is also a distinction between Tier I and Tier II. Human Noncancer Values (HNVs) for the Tiers are again distinguished on the basis of the available database. All relevant and available data must be considered. The

minimum acceptable data base for derivation of a Tier I criterion is at least one well conducted (see section II of the Human Health TSD—Minimum Data Requirements, Appropriate Study Design and Data Development, for a discussion of a "well conducted study") subchronic mammalian study. The duration of the study must be at least 90 days in rodents, or 10 percent of the lifespan of other appropriate species. The studies ideally should establish a dose response, i.e., a frank-effect level (FEL)—a level at which severe adverse effects or death occurs—as well as a LOAEL and NOAEL. Generally, the minimum data point used for decision making is a NOAEL; however, one exception to the requirement of using only a NOAEL is the use of a LOAEL involving mild, reversible effects, which may be considered acceptable from longer term studies where a NOAEL may not be available. (For example, a slight decrease in body weight may be considered a minimal LOAEL or possibly a NOAEL depending on other observed effects in a study, and whether the effects can be linked to the chemical in question.)

For Tier II values, as with Tier I criteria, all relevant available data must be considered. In developing Tier II values, the absolute minimum acceptable database is a well conducted repeated dose mammalian study of at least 28 days. The 28 day study was chosen as a minimally acceptable test that can yield sufficient information upon which to derive a Tier II value. It is also a study length used by the Organization for Economic Cooperation and Development in their guidelines for testing the safety of chemicals and by EPA's Office of Prevention, Pesticides and Toxic Substances to evaluate toxicity of chemicals. In some cases, the most critical effect of a chemical will take place well before a 90 day exposure that is, the acute effects of the chemical are of greatest concern. When high levels of a chemical over a short-term exposure can cause adverse effects, the results of a 90 day or longer-term study at low doses may not identify the critical acute effect identifiable after an acute high-dose test. In these cases, even in deriving a Tier I criteria, the most sensitive endpoint must take precedence over a less stringent 90 day test result.

Results from short-term studies can be correlated to longer-term study results, albeit to a limited degree (Weil and McCollister, 1963, Relationship Between Short- and Long-Term Feeding Studies in Designing an Effective Toxicity Test, Agricultural an Food Chemistry. 11(6): 486–491). Weil and McCollister were able to predict minimal effect levels for two-year exposures from short-term test results. Their assessment was not endpoint-specific, but rather correlated to the ratios between duration and any adverse effect.

Again, in using a 28 day study, the study should ideally produce a dose response curve, including a FEL, LOAEL and NOAEL. (EPA acknowledges that in many studies only a LOAEL and NOAEL will be observed, and in some cases only one or the other.) However, the minimum acceptable data point for decision making on such short term exposure data must be a NOAEL. In addition, the study ideally should be designed to observe all possible systemic effects and include examinations for histopathology. EPA does not believe studies which just examine behavioral changes or body weight changes would be acceptable as the basis for developing a Tier II value. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies may be more appropriate in some cases for derivation of Tier II values. Use of a particular LOAEL should be supported by the following information: Severity of effect, quality and duration of the study. EPA does not want to preclude the use of LOAELs from studies slightly longer than the required 28 day studies (such as 30 day tests) if the LOAEL from such a study represents an effect which is mild, reversible, close to a probable or actual NOAEL, and representative of effects observed over chronic exposures.

When the Tier II methodology is used to derive a HNV, an additional uncertainty factor of up to 10 may be applied in deriving the ADE. This factor is intended to account for the difficulties in extrapolating from a short term NOAEL to a long-term NOAEL. Structure activity relationships (SARs), and all other available data on the chemical should be used to determine the appropriate additional uncertainty factor. An SAR compares a chemical with substances that have structural similarities in order to predict whether the chemical might cause similar toxic effects. The EPA Office of Prevention, Pesticides and Toxic Substances has developed an SAR approach for assessing the hazards of chemicals for which very little data exist. For details on this EPA approach, refer to two journal publications: Auer, C., J. Nabholz and K. Baetcke, 1990, Mode of Action and the Assessment of Chemical Hazards in the Presence of Limited Data: Use of Structure-Activity Relationships (SAR) under TSCA, Section 5, Environ. Health Persp., Vol. 87, pp. 183–197; and Auer and Gould, 1987, Carcinogenicity Assessment and the Role of Structure Activity Relationship (SAR) Analysis under TSCA Section 5, Envir. Carcino. Revs. (J. Enviro. Sci. Hlth.) C5(1), 29–71.

The issue of whether to propose a Tier II HNV human health methodology was one of considerable debate within the Initiative Committees. In particular, there was concern that use of a 28 day, or other subacute study with the use of additional uncertainty factors, may result in underprotective values, since such short-term studies typically do not reveal evidence of other possible adverse effects resulting only from longer-term exposure. EPA requests comments on this issue. EPA also requests comments on whether the use of a Tier II human health methodology is appropriate and on the specific approach proposed in today's notice. EPA is particularly interested in other possible and practical Tier II methodologies, or in practical options to the use of a Tier II methodology to address lack of optimal well-developed databases. Finally, EPA invites comment on whether or not even shorter term studies, such as 14 day studies, might effectively be used in a Tier II HNV approach.

EPA is now conducting research on the correlation of short-term study results to long-term chronic test results. This research will entail an extensive evaluation of several scientific databases which include 14 day, 28 day, 90 day and two year study results. Data from these studies will be analyzed qualitatively and quantitatively (a number of options are being explored, such as categorical regression analyses or analyses of ratios or specific endpoints) to determine if shorter-term study results will adequately predict toxic effects associated with long-term exposures. For example, one proposed option is to divide 28 day NOAELs (or LOAELs) by a duration scaling factor to obtain a corresponding chronic value and then apply an appropriate uncertainty factor. These results could then be compared to short-term and long-term data for other chemicals to validate the predicted outcome of a particular model.

If the findings of EPA research appear relevant to today's proposed Tier II methodology, EPA expects to issue a notice of availability of the results of this research for consideration by the public in commenting on today's rule.

One option which EPA is considering as an alternative or supplement to the proposed Tier II approach is to screen a chemical initially using EPA's SAR evaluation approach (see Auer, C., J. Nabholz and K. Baetcke, 1990, Mode of

Action and the Assessment of Chemical Hazards in the Presence of Limited Data: Use of Structure-Activity Relationships (SAR) under TSCA, Section 5, Environ. Health. Persp. 87:183–197. EPA requests comments on other methods of conducting SARs. The SAR approach would be used to determine whether a related chemical could serve as a surrogate for the chemical for which there is little or no data. This approach could be used to either set a Tier II value based on surrogate chemical data or to justify further data development, as described below. EPA requests comments on the appropriateness of using surrogate chemicals to develop Tier II values.

For example, if an SAR indicates that a chemical is somewhat similar in structure to a class of chemicals which are extremely toxic or potent carcinogens, States could develop a Tier II value if a clear surrogate chemical existed or could be required to conduct or require permittees to conduct additional toxicity testing, such as the 28 day study now required by Tier II and/or additional studies on reproduction, neurotoxicity, or even longer-term studies as if a surrogate could not be identified. The intent of this alternative Tier II approach would be to require testing only for those chemicals of concern for which a surrogate cannot be determined and to avoid unnecessary testing for chemicals of very low health concern, as indicated by SAR. EPA requests comments on the feasibility and on the scientific merit of such an alternative option.

7. Criteria Derivation

The Tier I human cancer criteria or Tier II value is calculated as follows:

$$HCV = \frac{RAD \times BW}{WC + (FC \times BAF)}$$

Where:

HCV=Human Cancer Value in milligrams per liter (mg/L).

RAD=Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to 1 in 100,000.

BW=Body weight of an average human (BW=70kg).

WC=average per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies (WC_d=two liters/day) and average per capita incidental daily water exposure for surface waters not used as public water supplies (WC_r=0.01 liters/day).

FC=mean consumption by regional sport fishers of regionally caught freshwater fish=0.015 kg/day.

BAF=bioaccumulation factor derived through use of the BAF methodology in Appendix B of today's proposal.

The Tier I human noncancer criteria or Tier II value is calculated as follows:

$$HNV = \frac{ADE \times BW \times RSC}{WC + (FC \times BAF)}$$

Where:

HNV=Human noncancer value in milligrams per liter (mg/L).

ADE=Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC=Relative source contribution factor of 0.8 for bioaccumulative chemicals of concern. This is generally used for bioaccumulative organic compounds to allow for potential exposure via sources other than consumption of contaminated water and fish recreational exposure.

8. Proposed Criteria and Values

Proposed 40 CFR part 132, Table 3, sets forth HCVs and HNVs which have been derived using today's proposed methodologies for 20 chemicals or classes of chemicals. Note that for each HCV and HNV, two criteria are provided. The first is that which applies when exposure is from recreational activities and consumption of aquatic organisms. The second is that which applies when exposure is from consumption of aquatic organisms, drinking water and recreational activities. EPA requests comments on the proposed HCVs and HNCs in Table 3 of proposed 40 CFR part 132. The administrative record for this proposal contains technical support documents describing the details of derivation of each criterion and value.

One of the chemicals for which EPA has derived a proposed HNV and proposed HCV is 2,3,7,8-tetrachlorodibenzo-p-dioxin ("dioxin"). EPA is currently conducting a major new dioxin research and analysis effort, the results of which could not be reflected in today's proposal. If the results of this study become available prior to finalizing today's proposed rule, EPA expects to publish a notice of availability and solicit comment on whether the proposal should be modified to reflect this new information. If the results of the study are not available before EPA issues a final rule, EPA may consider delaying publication of a final dioxin criterion to ensure that it reflects the latest scientific information. Alternatively, EPA could finalize the dioxin criteria and modify them as necessary when the human health component of the ongoing studies is complete. If EPA choses this alternative, EPA believes that the antibacksliding provisions of the Clean Water Act will not prevent adjustments to the criteria. Readers are referred to section II of this preamble for a full discussion of this issue. EPA invites comment on the approach it should take to establishing dioxin criteria pending completion of its ongoing dioxin studies.

C. Relationship of the Great Lakes Initiative Guidelines to National Guidelines Revisions

As stated above, much of the Great Lakes methodology for deriving human health criteria is based on the 1980 methodology and advances in the science since 1980. Concurrent with the development of the Great Lakes Guidance, EPA is also in the process of reviewing and revising the 1980 National Guidelines which would apply to development of EPA National water quality criteria under section 304(a) of the Clean Water Act. It is expected that many aspects of today's proposed Great Lakes Guidance that differ from the 1980 National Guidelines will be proposed as part of the revised National guidelines. For instance, EPA may propose factors such as incidental exposures from recreational activities, a relative source contribution for some or all pollutants that accounts for exposures through non-surface water pathways, use of a fish consumption rate corresponding to the mean for sport angler consumers, and Tier II values development methodologies, unless, in the development of final Great Lakes Guidance or in the proposed or final revised National guidelines, there are new data or persuasive comment that would lead to directing a change in policy and decisionmaking.

All public comments received on the Great Lakes Guidance will be integral to preparing proposed revisions to the National guidelines. It is currently expected that a proposed revision to the National guidelines will be published in the **Federal Register** in 1993 and that there will be a separate opportunity for public comment on that proposal.

With respect to every change from the methodology in the current 1980 National Guidelines that is proposed today, EPA is considering the possibility of making no change from the current methodology. Accordingly, EPA requests comments on the possibility of retaining the approach set forth in the 1980 National Guidelines with respect to each individual component of today's

proposal that differs from the current National guidelines.

D. Comparison With the Clean Water Act and Great Lakes Water Quality Agreement

As mentioned earlier in section III.D (Aquatic Life), the CPA states that the proposed Guidance shall be no less restrictive than the provisions of the Clean Water Act and National Water Quality Criteria and Guidance. The CPA also specifies that the Guidance is to conform with the objectives and provisions of the Great Lakes Water Quality Agreement. The discussion below addresses conformance of the proposed human health methodologies and criteria with these requirements.

1. Tier I Human Health Criteria/ Methodology

a. *Comparison With the Clean Water Act.* Under the authority of section 304(a)(1) of the Clean Water Act, EPA established the 1980 National Guidelines, to be used in deriving National human health criteria. EPA believes that although today's proposed Tier I human health criteria methodology and the criteria proposed thereunder are not identical to the 1980 National Guidelines and individual National criteria in all details, they are generally no less restrictive.

First, as discussed above in this section of the preamble, EPA is proposing in today's notice Tier I human health criteria for 20 pollutants for which National criteria exist. These pollutants include a broad section of chemicals of concern proposed by the Initiative Committees to test the proposed methodology. Although today's proposal includes only these 20 pollutants while National human health criteria are currently available for over 90 pollutants, EPA believes that this approach will not result in less stringent levels of control. This is because under the implementation scheme proposed today, Great Lakes States would be required to derive criteria and values for these pollutants and for all other pollutants except those listed in Table 5 of part 132 whenever sufficient data exist to meet Tier I or Tier II minimum data requirements and the State determines that it is necessary to control these pollutants. Thus, the scope of the proposal in terms of pollutants covered is actually broader than the current National Guidance.

Furthermore, because the Tier I criteria for human health proposed today assume a higher fish consumption rate than the National criteria and use BAFs rather than BCFs to calculate fish tissue residues, the proposed numeric criteria are equivalent to or more restrictive than the current National criteria, with one exception. The proposed drinking water criterion for cyanide is slightly higher (i.e., less stringent) than the National cyanide criterion. The proposed cyanide Tier I human health criteria for drinking and nondrinking waters are based only on noncancer effects. Although both today's proposed cyanide criteria and the National cyanide criteria are based on the same study, there is a small difference between the criteria due in part to the different fish consumption rate and in part to rounding of the ADE and the criterion itself. EPA requests comment on the option of promulgating the drinking water National criterion for cyanide.

Additional Guidance provisions and measures will further enhance consistency with the Clean Water Act. Specifically, EPA is proposing elsewhere in today's Guidance a procedure to review State-calculated Tier I criteria for consistency with the Tier I methodology. In addition, the proposed Guidance contains a requirement for State adoption as standards of any Tier I criterion that EPA publishes in the future. These provisions are intended to ensure consistency with the Clean Water Act and to promote consistency in regulation throughout the Great Lakes System.

b. *Conformance With the Great Lakes Water Quality Agreement.* For the reasons stated in section III.D (Aquatic Life) of this preamble, EPA believes that today's proposal conforms to the General Objectives of the Agreement regarding the elimination or reduction of discharges into the Great Lakes System. For the 20 pollutants for which Tier I human health criteria are being proposed in today's notice, the Agreement does not specify numeric water quality criteria for the protection of human health. The Agreement does specify levels in the edible portion of fish that should not be exceeded for the protection of human consumers of fish for heptachlor/heptachlor epoxide and lindane.

As stated earlier, EPA believes that the Guidance criteria and methodologies proposed herein should serve as a basis to amend and supplement the Great Lakes Water Quality Agreement, as proposed by the Initiative Committees.

2. Tier II Criteria Methodology

a. *Comparison With the Clean Water Act.* EPA's current guidance and regulations for water quality standards contain nothing directly analogous to the two-tier approach proposed today for human health. States currently have very broad discretion when regulating pollutants that are subject only to narrative criteria. EPA believes that today's proposal is more rigorous than the current National requirements in this area because the proposed Tier II method derives generally more conservative values for non-cancer criteria to compensate for greater uncertainty in the database. Based on studies done to date, EPA expects that Tier II values will be more stringent than existing standards for these pollutants in most cases. Further, this approach imposes a structure to the process of translating narrative criteria into numeric values. Finally, today's approach will result in more uniform control of pollutants lacking National standards in the Great Lakes States.

b. *Conformance With the Great Lakes Water Quality Agreement.* EPA believes that the Tier II methodology is consistent with the General Objectives of the Agreement. Moreover, it serves as a translator mechanism of the States' narrative water quality standards. The Tier II methodology will enhance regulatory efforts in the Great Lakes basin, will serve its purpose of promoting consistency in the regulation of toxics in the Great Lakes basin, and is therefore also in conformance with the Agreement.

E. Review of the Great Lakes Guidance by the EPA Science Advisory Board (SAB)

The SAB reviewed the Human Health proposal for the Great Lakes Guidance presented today. Their complete findings and opinions are reported in an EPA document entitled, "An SAB Report: Evaluation of the Guidance for the Great Lakes Water Quality Initiative", EPA–SAB–EPEC/DWC–93–005, December 1992, which is available in the administrative record for this rulemaking.

The SAB commented that the tiered approach offers a mechanism for improving EPA's data base to reduce uncertainties and to develop appropriate data for GLWQI compounds for which National criteria do not exist. EPA agrees with this comment. The intent of the two-tiered approach was to develop water quality standards and permit values for chemicals of concern and to also promote the development of data needed to complete data bases in developing criteria.

The SAB also commented that the tiered approach has the potential to be frivolously applied to chemicals regarded as safe. EPA believes that if the proposed Great Lakes Guidance were applied literally, without applying basic

toxicologic judgement, there is the potential for misapplication. However, the tiered approach is being applied to chemicals which are considered hazardous in the basin, of which there are approximately 140. It is unlikely that criteria will be developed for chemicals such as sugar or fatty acids. In addition, the Great Lakes Guidance does not establish a rule that criteria will be developed for all chemicals for which data exist. Criteria or values are to be developed for the list of 140 which are deemed "chemicals of concern" in the Great Lakes basin.

Additionally, the SAB noted that it is not possible to argue that Tier I chemicals protect against reproductive/developmental or carcinogenic endpoints because the minimum data base does not require data appropriate to estimate such hazards. EPA's response is that it is true that the Tier I requirements do not require, at a minimum, all data for all possible effects. However, the goal of Tier I is to evaluate all available data before developing a HNV or HCV. In addition, the Great Lakes Guidance attempts to track very closely with established EPA cancer and noncancer guidelines for evaluating data and establishing safe daily levels. Presently, if the only existing data is noncancer, subchronic data (e.g., 90 day study), EPA allows development of an RfD as long as uncertainty factors are used to compensate for lack of reproductive/developmental data.

The use of uncertainty factors does not take the place of well-run reproductive/developmental studies. It merely assumes that if a reproductive study was conducted it may result in a slightly lower NOAEL or LOAEL. Hence, the practice of using an extra uncertainty factor of 3 for lack of reproductive/developmental data by the RfD work group.

With regard to an adjustment in Tier I for a lack of carcinogenic data, Tier I cancer criteria are only developed if the chemical is considered a Group A, B, or C carcinogen by EPA's CRAVE group. When there is a lack of carcinogenic data, a Tier II value may be developed if the chemical is considered a Group C carcinogen and enough data is available to develop a q^{1*}.

Placing a chemical lacking in reproductive/developmental and/or carcinogenic data in Tier II may help to generate such data but would also present an inconsistency with previously promulgated EPA drinking water standards. Many compounds regulated under the Safe Drinking Water Act are Group D chemicals: Not enough data available to make a carcinogenicity evaluation. EPA acknowledges that it is important to strike a balance between the need to regulate a chemical, if it is regarded as a human health concern, and the need to complete the toxicological data base for a particular chemical.

The suggestion that well-characterized Group C chemicals that arguably do not pose a cancer threat be regulated on a noncancer basis is an option which has been raised in the GLWQI proposal.

The SAB further stated that conflict may arise if criteria are developed for disinfectants and disinfection by-products. EPA realizes there are potential conflicts related to the regulation of chlorine and chlorinated by-products. However, if disinfection by-products are toxic to humans, aquatic organisms and/or wildlife, then industrial or municipal discharges of chlorine, chloramines or by-products should be controlled by Great Lakes Initiative criteria. In many cases, disinfection of wastewater may be necessary to maintain a use designation (e.g., swimmable). However, if chlorination results in the loss of fish, wildlife and a fishable use designation, the reduction of chlorination by-products will be required through GLWQI criteria. Clearly, a balance will have to be struck in the development of criteria which serve as the basis for conflicting designated uses.

The SAB also commented that the GLWQI Guidance may conflict with existing National guidelines and criteria. EPA acknowledges the potential for confusion. In reviewing and revising the 1980 methodology for developing human health criteria, EPA is closely examining the requirements of the GLWQI. However, it must be noted that the GLWQI Guidance is based on the combination of basic National methodology guidelines for conducting risk assessment with regional exposure assumptions.

With regard to thresholds for carcinogens, the SAB stated that the method by which low dose extrapolation is conducted should not be viewed as simply threshold or nonthreshold carcinogens. Mechanisms of action should be considered. The Human Health TSD presents text from EPA's 1986 cancer guidelines which recommends the evaluation of mechanistic cancer and pharmacokinetic data in assessing carcinogens and models to be used in quantifying the potency. The TSD includes a level of subtlety with regard to carcinogenicity not present in the regulation and preamble.

Further, the SAB noted that with regard to a Minimum Data Base, Tier I and II should develop separate values for Group C chemicals depending on the available data. Tier I should only be reserved for Group C chemicals which have been adequately tested and which do not support the notion that they are probable human carcinogens. Tier II should include chemicals which have been tested in only one species. EPA's response to this comment is that the GLWQI Guidance allows for the development of Tier I or II values for Group C chemicals depending on the available data. The distinguishing factors focus on whether enough data exist to conduct a potency estimate and whether a dose response actually exists. To restrict Tier I to only those chemicals which have been adequately tested may be too limiting and may ultimately result in under protecting human health. EPA acknowledges that there may be cases where a chemical is so well tested that it does not appear to be a possible human carcinogen. To address this situation, EPA has proposed the option of regulating some Group C chemicals using a noncancer endpoint with an additional uncertainty factor to account for possible carcinogenicity.

Another SAB comment states that with regard to the Tier II concept, a 28 day test may not detect some human health effects especially for chemicals with long latency periods. EPA realizes the use of a 28 day NOAEL may be marginal for detecting some chronic human health effects and is conducting research in this area over the next year to determine whether the 28 day data are a reliable minimum data point. EPA is also restricting the development of Tier II values to results of 28 day studies which have examined systemic effects and ideally provided some histopathological examination.

The SAB also commented that with regard to the use of a Relative Source Contribution, an 80 percent RSC is not supportable because it is within the rounding error on the calculations of the overall exposure. In addition, other sources should already be compensated for in the calculation of fish consumption. EPA's response to this comment is that the use of an RSC was incorporated to account for other sources that may contain the chemical besides fish. In the case of pesticides, for example, many agricultural or dairy products may contain a pesticide in quantities large enough to make the RSC concept important. It is true that the 80 percent may be within the rounding error for the calculation of the overall exposure, but the intent was to reduce

the criteria by 20 percent in the case of a bioaccumulative chemical. In essence, the 20 percent reduction serves as a safety factor to protect against other possible sources of the chemical which have not been explicitly accounted for. This is the same process (setting a default RSC of 20 percent when data on other sources does not exist) which is done in developing drinking water standards, which has been approved by the SAB in its review of drinking water standards.

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VI. Wildlife

A. Introduction

For the purposes of the proposed Great Lakes Water Quality Criteria Guidance, "wildlife" is defined as species in both Taxonomic Classes, Aves and Mammalia (birds and mammals). The proposed Guidance for deriving wildlife criteria and values is included in appendix D of the proposed Guidance. The Technical Support Document for Wildlife Criteria is an appendix to this preamble. The actual criteria documents which provide the data and the derivation of the individual criteria are available in the administrative record for this rulemaking. EPA's expectations for determining whether a State's water quality standards are consistent with the Guidance are set forth in § 132.6 of the proposed Guidance.

In the case of toxic chemicals, terminal predators such as otter, mink, gulls, terns, eagles, ospreys and kingfishers are at risk from contaminants in Great Lakes waters. In addition to direct exposure via drinking

the water, species at higher trophic levels are exposed to toxic substances through the food web as the chemicals proceed upward via biomagnification. Contaminants which are almost undetectable in lake water may be magnified hundreds of thousands of times within the flesh of fish and magnified still further in a carnivorous bird or mammal which consumes contaminated fish out of the Great Lakes.

Because wildlife species are at the top of the food web, current criteria derived to protect fish, which live in the water, may be inadequate to protect high-level wildlife consumers of contaminated fish. Wildlife are especially at risk from chemicals which biomagnify because they are frequently exposed to very high levels of the contaminants since they reside at the apices of aquatic food webs. For this reason, emphasis was placed on selecting piscivorous wildlife species (i.e., those which eat fish) for the derivation of wildlife criteria as representative of species likely to experience significant contamination through an aquatic food web. Wildlife species may also have unique metabolic pathways which make them more susceptible to the toxicity of a chemical than aquatic species.

Research on wildlife species resident in the Great Lakes indicates that wildlife populations are threatened in areas of high contamination by toxic chemicals. In the Great Lakes, reproductive impairment of numerous wildlife species has been correlated with the presence of PCBs, DDT and its metabolites, and other contaminants. In the 1960s, mink fed a diet of Great Lakes fish suffered complete reproductive failure. Detailed laboratory investigation revealed that the causative agent was PCBs in Great Lakes fish. The overall reproductive success of bald eagles is much lower along lake shore areas of the Great Lakes than in inland nesting territories.

There is additional discussion located in the section I (Background) of this preamble on the impacts of toxic chemicals on wildlife in the Great Lakes. Numerous studies confirm the adverse effects of pollution on Great Lakes wildlife and support the need for water quality criteria formulated for their protection. It is because of the numerous impacts of toxic chemicals observed in wildlife in the Great Lakes and the inconsistencies among the Great Lakes States and Tribes in addressing wildlife impacts, that the Steering Committee, Technical Work Group, and EPA agreed there was a need for generation of separate wildlife criteria as a part of the Great Lakes Water Quality Initiative (GLWQI). This provides the rationale for proposing specific wildlife standards in this Guidance.

EPA has ample authority to develop criteria and methods specifically directed at protecting wildlife from threats originating in Great Lakes waters. Section 118(c)(2)(A) of the Clean Water Act requires EPA to develop numerical limits on pollutants in Great Lakes waters to protect wildlife as well as human health and aquatic life. Similarly, provisions of the Great Lakes Water Quality Agreement of 1978 require the United States and Canada to protect wildlife. For example, Article III of the Agreement established a "General Objective" of freeing the Great Lakes System from substances resulting from human activity that will adversely affect waterfowl.

Moreover, several of the "Specific Objectives" for individual pollutants set out in Annex I of the Agreement also set limits which should not be exceeded in order to protect fish-consuming birds and animals. These are presented as fish tissue concentrations or water concentrations as follows: DDT and its metabolites in whole fish should not exceed 0.3 micrograms per gram (wet weight basis), the concentration of total PCBs in whole fish should not exceed 0.1 micrograms per gram (wet weight basis), and the concentration of total mercury in whole fish should not exceed 0.5 micrograms per gram (wet weight basis). The "Specific Objectives" which present water concentrations which should not be exceeded for the protection of fish-consuming birds and animals are: the total concentration of DDT and its metabolites should not exceed 0.003 micrograms per liter; and mirex and its degradation products should be less than detection levels as determined by the best scientific methodology available.

Section 304(a)(1) of the Clean Water Act also authorizes EPA to develop criteria that protect wildlife for all waters of the United States. As explained in more detail later in this section of the preamble to this rule, EPA has not yet issued any nationally applicable criteria targeted solely at the protection of wildlife. Rather, EPA incorporated consideration of wildlife impacts into the 1985 methodology for developing criteria for aquatic life (Stephan, et. al., 1985).

The proposed Guidance relating to wildlife criteria was developed as part of the GLWQI. The Technical Work Group and the Steering Committee are collectively referred to within this portion of the preamble as the Committees of the Initiative. The Committees of the Initiative assigned the lead in developing an initial proposal for deriving criteria to protect wildlife for the Great Lakes Guidance to the State of Wisconsin. The procedure proposed by the Wisconsin Department of Natural Resources was modified through discussions in the Committees of the Initiative and modified and approved by EPA.

In developing the methodology for deriving wildlife criteria for the GLWQI, the Wisconsin Department of Natural Resources, Bureau of Water Resources Management, obtained scientific guidance from participants in a one-day workshop (the Workshop) held in Madison, Wisconsin, November 8, 1990. Wildlife research toxicologists and biologists representing academia, State governments, the U.S. Fish and Wildlife Service and EPA were invited to participate in the Workshop. Representatives of the regulated community were also present at the Workshop.

B. Wildlife Criteria Methodology

Like the aquatic life and human health criteria methodologies described above, EPA is proposing a two-tiered approach for the Great Lakes Water Quality Guidance for Wildlife, which will hereinafter be referred to as Tiers I and II. EPA is proposing to require all Great Lakes States and Tribes to apply the methodology to derive Tier I criteria and Tier II values, as well as the Tier I numeric criteria proposed, to discharges into the Great Lakes System. The Committees of the Initiative developed, and EPA is proposing, a Tier II method that is very similar to the proposed Tier I method. However, because Tier II values are based on a less extensive data base than are Tier I criteria, the uncertainty factor which accounts for interspecies toxicological differences (the Species Sensitivity Factor) may be smaller than that used in deriving a Tier I criteria. In deriving Tier II values, the Species Sensitivity Factor may also account for interspecies toxicological differences across taxonomic classes. This uncertainty factor is intended to address any uncertainties stemming from the use of a less inclusive database and its use is meant to produce Tier II values that are conservative.

Tier II values are intended to be conservative to encourage data generation so a Tier I criteria can be calculated. Although States and Tribes have the authority at their discretion to do so, EPA does not intend that Tier II values will be adopted into State standards, but, rather, will serve as a translator mechanism for interpretation of the State's narrative criteria (e.g., no

toxic pollutants in toxic amounts) and as a basis for developing control measures such as effluent limitations in NPDES permits. In the future, EPA may replace Tier II values with Tier I criteria as more data are generated.

1. Wisconsin State Wild and Domestic Animal Criteria

The Committees of the Initiative chose, as the starting point for the development of the wildlife criteria methodology, the Wild and Domestic Animal Criteria (WDAC) approach developed by the State of Wisconsin (Wisconsin Administrative Code NR 105.07, 1989; Technical Support Document for NR 105, 1988), which is available in the administrative record for this rulemaking. A WDAC is the lowest species wild and domestic animal value (WDAV) calculated using the equation presented below. The equation used to derive the WDAV portrays a "model animal" as follows:

$$WDAV = \frac{NOAEL \times Wt_A \times SSF}{W_A + (F_A \times BAF)}$$

where: WDAV is the wild and domestic animal value in milligrams per liter (mg/L); NOAEL is the no observable adverse effect level in milligrams of substance per kilogram of body weight per day as derived from mammalian or avian studies (mg/kg-d); Wt_A is the average weight in kilograms (kg) of the test animals; W_A is the average daily volume of water in liters consumed per day (L/d) by the test animals; SSF is the species sensitivity factor which is an uncertainty factor ranging between 0.01 and 1 to account for differences in species sensitivity; F_A is the average daily amount of food consumed by the test animals in kilograms (kg/d); and BAF is the aquatic life bioaccumulation factor with units of liter per kilogram (L/kg).

2. Modifications to Wisconsin's WDAC Procedure

As mentioned, the proposed Guidance on a water quality criteria methodology for wildlife is based on the State of Wisconsin's wildlife criteria procedure. However, the Initiative Committees and EPA developed several modifications of this State procedure which EPA is proposing to incorporate into the proposed Guidance. They include: A requirement that States and Tribes use specific Great Lakes species identified by EPA as representatives of regional wildlife species likely to experience significant exposure from the aquatic food web rather than using a "model animal"; provisions that more clearly define and make more stringent toxicity data requirements (i.e., a dose-response study is required); provisions which allow a subchronic to chronic uncertainty factor to be applied to the NOAEL to extrapolate from subchronic to chronic exposure lengths; and provisions for two tiers of criteria rather than one as under the Wisconsin approach. A fifth modification to the approach submitted by Wisconsin is proposed in procedure 1 of appendix F to part 132 of this proposed Guidance (the site-specific modification portion of Great Lakes Water Quality Guidance Implementation Procedures). Procedure 1 allows for the incorporation of an additional uncertainty factor into the equation to account for intraspecies variability in the derivation of a species-specific wildlife criterion or value for a species other than the representative species proposed for general use. See section VIII.A of this preamble for a discussion of the additional uncertainty factor in the proposed procedure 1 of appendix F, as well as alternative text, upon which EPA invites comment, that provides additional guidance to States and Tribes.

3. The Great Lakes Water Quality Initiative Wildlife Criteria Methodology

The approach used in the aquatic life criteria methodology, where the aquatic life criterion is determined from a statistically valid distribution of toxicity values for a number of aquatic species, is not currently feasible for the derivation of wildlife criteria. This is because there is a less extensive and representative wildlife toxicity database and limited information on species-specific exposure parameters. The wildlife criteria methodology is more similar to that employed in the calculation of noncancer human health criteria.

The general procedure as well as the requirements for developing wildlife criteria and values are provided in appendix D to part 132. The Technical Support Document (TSD) provides additional background as well as guidance on the selection of values for uncertainty factors which may be used in the derivation of wildlife criteria. EPA believes that the States, the Tribes and the public would benefit from easy access to the background material provided in the TSD because the wildlife criteria are so new. EPA, however, acknowledges that the TSD repeats some of the material that appears in the Method. EPA also is concerned that the States, the Tribes and the public may become confused and mistakenly believe that the TSD also sets out binding requirements. Consequently, EPA is considering either (1) combining the TSD with the Method for publication in the CFR, or (2) publishing only the Method in the CFR and distributing the TSD widely. EPA invites comment on this issue. If option (1) is pursued, EPA invites comments on whether there are any components of the TSD which should not become binding requirements.

As with the human health methodology, the wildlife methodology has both a hazard and an exposure component. The hazard component is determined from the toxicity data for a given pollutant and the exposure component is determined from species-specific exposure parameters.

a. *Parameters of the Hazard Component of the GLWQI Wildlife Criteria Methodology.* The Committees of the Initiative discussed various aspects of the hazard component of the final wildlife criteria methodology. EPA is proposing to adopt the ideas they developed on several aspects of the hazard component of the wildlife method which are presented below.

i. *LOAEL to NOAEL Extrapolations.* In some studies when a range of doses are used, an effect is observed at the lowest chemical concentration used in the study. The proposed Guidance proposes to allow use of an uncertainty factor that would permit a NOAEL to be estimated from the LOAEL determined in such a study. Experimental support for this concept is referenced in the Technical Support Document for Wildlife Criteria (the appendix to this preamble), as well as appendix A to the Great Lakes Water Quality Initiative (GLWQI) Technical Support Document for Human Health Criteria and Values, which is available in the administrative record for this rulemaking. Copies are also available upon written request to the address listed in section XIII of this preamble. EPA notes that use of such an adjustment factor is permitted within the existing human health water quality criteria process (45 FR 79353–79354, November 28, 1980; and 50 FR 46944–46946, November, 13, 1985). EPA is proposing to allow this adjusted NOAEL value to be used in the derivation of both Tier I wildlife criteria and Tier II wildlife values. EPA requests comment on this approach.

ii. *Subchronic to Chronic Extrapolations.* The wildlife criteria methodology allows for application of an uncertainty factor to adjust the NOAEL from a subchronic study to estimate a chronic NOAEL. Because of toxicokinetic considerations, bioassays that are of insufficient duration to encompass a significant portion of an organism's life span or a sensitive life stage may underestimate hazards. EPA

proposes providing the option of considering exposure length by extrapolating from subchronic studies to estimate chronic impacts. As presented in the Technical Support Document for Wildlife Criteria (the appendix to this preamble), the value of this term must be based on the bioaccumulative potential of the chemical, toxicokinetic considerations, test length and available test data. The value applied can range from 1.0 to 10, adopting the 10-fold uncertainty factor value applied in the derivation of human health criteria as the upper limit for the value. Endorsement of this approach by EPA is referenced in the Technical Support Document for Wildlife Criteria (the appendix to this preamble), and experimental support for this approach is referenced in appendix A to the GLWQI Technical Support Document for Human Health Criteria and Values. EPA requests comments on the provisions to allow for such adjustments to the NOAEL in the derivation of wildlife criteria.

iii. *Species Sensitivity Factor.* In the derivation of noncancer human health criteria, an uncertainty factor is applied when extrapolating from results of long-term studies on experimental animals to humans. EPA is proposing to allow use of a species sensitivity factor (SSF) which adjusts for the same type of uncertainty—differences in toxicological sensitivity—among wildlife species. Specifically, it adjusts only for differences in toxicological sensitivity between the test species (the species from which the NOAEL is derived) and the representative wildlife species identified for protection or the species identified as requiring greater protection. (The SSF is not intended to adjust for differences with regard to body weight and food and water consumption rates between the test species and representative species or the species requiring greater protection.)

Guidance in the selection of a SSF value is provided in appendix D to part 132 and the Technical Support Document for Wildlife Criteria. The discussion of an interspecies uncertainty factor located in section C of appendix A to the GLWQI Technical Support Document for Human Health Criteria and Values may also be useful in determining the value of a SSF.

In its December 16, 1992, report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," (U.S. EPA, 1992), EPA's Science Advisory Board (SAB) recommended that the methodology for deriving wildlife criteria incorporate procedures that address a measure of the variability of species sensitivities observed in substance-specific studies. The guidance provided in the Technical Support Document for Wildlife Criteria for determining an appropriate SSF has been revised following submission to the SAB for review. The current guidance attempts to address the SAB's concerns and requires consideration of the amount and quality of available studies; the diversity of species for which data is available; known physicochemical, toxicokinetic and toxicodynamic properties of the chemical; and similar data for chemicals that operate by the same mode of action. EPA requests comment on the guidance provided in determining the value of a SSF.

For Tier I criteria, the Agency proposes that the SSF may be used to extrapolate toxicity data across species within each of the two taxonomic classes of Aves and Mammalia. An interclass SSF may be used for a given chemical for a Tier I criteria only if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, incorporating the endpoints in question, for a chemical analog that acts under the same mode of toxic action.

Participants at the Workshop discussed the range of values for SSFs. The Workshop concluded that, in nearly all cases, the available toxicological data for the determination of a SSF to be applied in the derivation of a Tier I criteria, or any value calculated using the Tier I approach, would result in a SSF within the range of 1.0 to 0.01. EPA is proposing to require that a SSF outside of this range for a Tier I criteria, or any value calculated using the Tier I approach, must be based on sound scientific and technical reasons and must be accompanied by a written justification presenting this reasoning. This justification should be provided to EPA by inclusion in the State's or Tribe's submission under § 132.5 of this proposed rule. Use of a SSF outside of this range is prohibited unless approved by EPA based on its consideration of the justification provided.

For Tier II wildlife values, EPA proposes that the SSF may be used to extrapolate toxicity data across the two taxonomic classes without the strict requirements presented above for use in deriving Tier I criteria. Because of the uncertainties associated with performing interclass extrapolations, and because Tier II values are intended to be conservative to encourage data generation, the SSF applied may not be greater than 1.0 but may be lower than 0.01. A written justification is not required when a SSF less than 0.01 is used in the derivation of Tier II values.

iv. *Intraspecies Variability.* Procedure 1 in appendix F to this Guidance discusses site-specific modifications to criteria/values and suggests the use of an additional uncertainty factor in the equation used to calculate Wildlife Values. Section VIII.A of this preamble presents a method for the use of this additional uncertainty factor, called an intraspecies uncertainty factor (ISF), to adjust for intraspecies variability in the development of site-specific criteria. The use of this additional uncertainty factor provides an additional level of protection when protection of all individuals in a given population is desired. The method presented in section VIII.A of this preamble proposes incorporation of an intraspecies sensitivity factor (ISF) into the hazard portion of the wildlife value equation. The following discussion provides more detail on the ISF proposed in appendix F and section VIII.A of this preamble.

The ISF is an uncertainty factor to adjust for intraspecies toxicological differences to protect sensitive individuals in a population. The National Academy of Sciences endorses the use of a 10-fold factor to account for differential sensitivities within the human population (NAS, 1980). A discussion of the experimental support for the application of an intraspecies uncertainty factor is provided in appendix A to the GLWQI Technical Support Document for Human Health Criteria and Values. Although chronic toxicological data for wildlife species are relatively scarce, EPA believes that the factor of 10 that EPA has developed to protect sensitive members of the human population will also protect sensitive members of wildlife species. EPA is proposing to allow the use of an ISF value of 10 without requiring the development of specific justification. EPA is proposing to require users who wish to use factors greater than 10 to develop specific and detailed scientific rationale for the factors they propose to use. The rationale must be submitted to EPA on request. EPA anticipates that users who have actual toxicological data from wildlife studies may be able to justify the use of greater ISFs. EPA is not proposing to permit the use of ISFs for wildlife that are less than 10.

In the December, 1992 Science Advisory Board (SAB) report (U.S. EPA, 1992), the EPA's SAB identified the need for wildlife criteria to be constructed so that, in special cases, they are able to protect the individual rather than the population. EPA believes incorporation of the ISF into the wildlife criteria methodology, as

proposed in section VIII.A. of this preamble, adequately addresses this concern. EPA invites comment on the ISF.

v. *Alternative Formula for Hazard Component of Equation.* In appendix D to part 132, the hazard component is represented by:

$$[NOAEL \times SSF]$$

The NOAEL applied in the equation may be: A NOAEL determined by applying a LOAEL to NOAEL uncertainty factor to a LOAEL; or a NOAEL adjusted to account for subchronic to chronic exposure durations by application of a subchronic to chronic uncertainty factor. In the equation, the NOAEL may be further adjusted to account for interspecies toxicological differences multiplication by of a SSF and/or intraspecies toxicological differences by division by an ISF. Because of these potential adjustments to the NOAEL which may be carried out in the calculation of a wildlife value, in this preamble EPA proposes a modification to the hazard component of the wildlife criteria calculation equation presented in appendix D to part 132. Rather than using the equation presented in appendix D to part 132, EPA requests comment on the replacement of the hazard portion of the equation (presented at the beginning of this section) with the formula presented below:

$$\frac{ED}{UF_S \times UF_C \times UF_E \times UF_I}$$

Where:

ED=the Effect Dose in mg/kg-d for the test species. This could be either a NOAEL or a LOAEL.

UF_S=Uncertainty Factor for extrapolating toxicity data across species. Because it appears in the denominator, the value of this term would be the inverse of the SSF described and defined in appendix D to part 132 and the appendix to this preamble.

UF_C=Uncertainty Factor for subchronic to chronic exposures. The value of this term would be the subchronic to chronic uncertainty factor previously described and discussed in appendix D to part 132 and the appendix to this preamble.

UF_E=Uncertainty Factor for LOAEL to NOAEL extrapolations. The value of this term would be the LOAEL to NOAEL uncertainty factor discussed in appendix D to part 132 and the appendix to this preamble.

UF_I=Uncertainty Factor for intraspecies toxicological differences to protect sensitive individuals in a population. Because it appears in the denominator above, this term would be the inverse of the ISF proposed in section VIII.A of this preamble, and discussed above in this section of the preamble.

In many cases, the value for these uncertainty factors may be one. That is, values other than 1.0 would rarely if ever be used for all uncertainty factors simultaneously. However, EPA believes that the alternative formula has the advantage that it more clearly presents the uncertainty factors employed. The equation used to derive wildlife criteria and values would be:

$$WV = \frac{\frac{ED}{UF_S \times UF_C \times UF_E \times UF_I} \times Wt_A}{W_A + (F_A \times BAF)}$$

The terms are defined above and in appendix D to part 132. This formula appears more similar to that used in the derivation of noncancer human health criteria. EPA requests comment on the adoption of the alternative formula in the final Guidance.

b. *Parameters of the Exposure Component of the GLWQI Wildlife Criteria Methodology.* In deriving human health criteria, the exposure estimates employed are for one species, *Homo sapiens.* The Committees of the Initiative and EPA, however, wanted to develop a wildlife method that would protect a broad range of wildlife species. There are two possible ways to accomplish this: Estimate exposure parameters for a hypothetical "model animal," (the approach implicit in the Wisconsin methodology); or select an actual wildlife species as a representative wildlife species. The Committees and EPA agreed to select representative species for the two taxonomic classes, Aves and Mammalia, in order to provide a basis for determining an appropriate SSF and incorporating empirical exposure parameters where available for specific species in each taxonomic class. Selection of representative species which are then used to derive criteria to protect wildlife is a significant issue. The criterion and selection process used to select the representative species is presented in section V of the Technical Support Document for Wildlife Criteria (the appendix to this preamble). The species selected are representative of Great Lakes basin wildlife which are likely to experience significant exposure to contaminants from aquatic food webs. EPA requests comment on the selection process and the results employed in the derivation of wildlife criteria.

i. *Approach Used to Select Representative Species Identified for Protection.* To select representative avian and mammalian species, an analysis of wildlife species that inhabit the Great Lakes basin was undertaken to identify those most likely to be exposed to environmental contaminants from aquatic ecosystems (these representative species are not necessarily the most toxicologically sensitive species). This analysis is presented in the Technical Support Document for Wildlife Criteria. With regard to mammalian species, results of this assessment suggested that, in general, piscivorous species are at greatest risk from the chemicals identified for wildlife criteria development (see section iii, below). Two mammalian species were chosen to represent the range of body weights and food habits of piscivorous mammals. Representative avian species were categorized based on three species-specific parameters: body weight, food habits (e.g., food source and prey size) and foraging styles. Based on available data, the results of this assessment suggested that, with the precision of available data, ingestion rates for birds were generally proportional to animal mass and not influenced by foraging style. Therefore, EPA is proposing to select representative avian and mammalian species which represent a range of body weights and food habits appropriate for the Great Lakes basin and which are likely to experience significant exposure from the aquatic food web.

EPA requests submission of peer-reviewed empirical exposure information for wildlife species residing in the Great Lakes basin which were not

referenced in the analysis presented in the Technical Support Document for Wildlife Criteria and which the commenter feels should be considered in the selection of representative avian and mammalian species.

As a result of applying this approach, the representative species proposed to represent avian and mammalian species of the Great Lakes basin which are likely to experience significant exposure to contaminants in aquatic ecosystems through the food chain are the mink *(Mustela vison)* and river otter *(Lutra canadensis)* and the belted kingfisher *(Ceryle alcyon)*, osprey *(Pandion haliatus)* and bald eagle *(Haliaeetus leucocephalus)*. EPA specifically invites comment on the choice of representative species identified for protection, and requests that the public document the basis for considering other species.

The SAB, in their December 1992 report (U.S. EPA, 1992), recommended that the approach to protect wildlife be expanded to consider ecologically representative species. EPA acknowledges that the approach used to select representative species does not consider potential impacts on wildlife species due to changes in communities or the ecosystems in which they reside and recognizes the need for research to better understand the large uncertainties which currently exist in this area. EPA welcomes suggestions on how to select ecologically representative species given the current state of knowledge.

ii. *Bioaccumulation Factors.* The procedure for determining the appropriate bioaccumulation factor (BAF) for calculation of Tier I wildlife criteria and Tier II wildlife values is presented in appendix B to part 132. Based on the food habits of the representative wildlife species, BAFs calculated for trophic levels 3 or 4 may be used. BAFs for invertebrates, aquatic plants or other trophic levels may also be used on a case-by-case basis based on their proportion in the total diet consumed by the wildlife species requiring greater protection.

iii. *Exposure Routes Considered.* The derivation of the equation used to calculate wildlife values, which are in turn used to calculate a wildlife criterion, considers oral exposure (i.e. food and water ingestion). EPA considers oral ingestion the most significant route of exposure for bioaccumulative pollutants and these pollutants represent the greatest risk to wildlife species. EPA requests comments on this assumption.

In its December 16, 1992 report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative" (U.S. EPA, 1992), EPA's SAB expressed concern that the wildlife exposure assessments in the proposed guidance do not consider exposures via inhalation or dermal contact which may be important for chemicals with significant vapor pressure and intermediate molecular weights. EPA solicits modifications of the proposed approach which would address these concerns and consider other significant routes of exposure for non-bioaccumulative chemicals.

C. Additional Issues

The sections below highlight some of the issues and discussions which occurred during the development of the wildlife criteria methodology proposed. EPA solicits comments on each of these issues.

1. Use of Human Health Paradigm

The December, 1992, SAB report (U.S. EPA, 1992) states that the wildlife criteria concepts were formulated around the perceived requirements of the human health paradigm and they are inadequate for wildlife. Adjustments made to the human health paradigm include: (1) Defining database requirements such as preferred test species, test length, and toxicological endpoints; (2) selection of species representative of wildlife species likely to experience significant exposure from aquatic food webs and for which empirical dietary exposure information was available; and (3) options for the use of various uncertainty factors to ensure protection of the distribution of wildlife species. Given the extent of current exposure and toxicological data available for wildlife species, EPA believes the methodology (presented in appendix D to part 132, and clarified in the appendix to this preamble and the criteria derived based on this methodology, are scientifically defensible. EPA requests comments on additional modifications to the proposed methodology which would improve its scientific defensibility.

2. Minimum Data Base for Wildlife Criteria Derivation

There was a considerable amount of discussion in the Committees of the Initiative and at the Workshop on the minimum toxicological database requirements for both Tier I criteria and Tier II values. Due to the uncertainties in extrapolating data across taxonomic classes, EPA is proposing to require that the minimum toxicity database for Tier I criteria must provide enough data to generate a subchronic or chronic dose-response curve for both birds and mammals. For Tier II values, the minimum toxicity database need only provide enough data to generate a subchronic or chronic dose-response curve for one taxonomic class (Aves or Mammalia). In all cases, any study used in the derivation of wildlife criteria or values should be peer-reviewed.

Additionally, if available, field studies of wildlife species shall take precedence over studies using traditional laboratory species in the development of wildlife criteria and values because uncertainties in extrapolating from laboratory to field impacts are reduced. Any laboratory studies used must use avian or mammalian species.

The oral exposure route is the primary route of exposure to be considered in selecting toxicity studies. EPA proposes that studies involving other exposure routes (e.g., dermal or inhalation) should be considered in the derivation of a Tier I criteria or Tier II value only when an equivalent oral dose can be estimated. Such an estimation should be supported by toxicokinetic and in vivo metabolism data. Without this supporting data, the mechanism of toxicity and/or the dosimetry for these routes of exposure cannot be assumed to be the same as for the oral route of exposure, and the criteria and value calculations are based on an oral route of exposure.

If laboratory studies are used to derive a Tier I criteria, EPA is proposing a 90-day requirement for any mammalian study and a 28-day requirement for any avian study. This is to ensure that the toxicity data on which a wildlife criterion is based does not underestimate effects associated with repeated exposures to a chemical.

If laboratory studies are used to derive a Tier II value, EPA is proposing the same requirements for Tier I except a 28-day mammalian study which meets the other requirements presented in appendix to part 132 may also be used.

3. Acceptable Endpoints for Toxicity Studies

The acceptable endpoints on which the NOAEL determined from the toxicity study must be based are defined in the wildlife methodology presented in appendix D to part 132. These endpoints were selected because they are parameters most likely to influence population dynamics. When more than one study is available which assessed different endpoints, EPA recommends that preference be given to studies which assess endpoints which best reflect potential impacts to wildlife populations.

EPA's SAB, in their December 16, 1992 report (U.S. EPA, 1992), recommended that EPA develop

guidance for the selection of NOAELs appropriate for the protection of wildlife populations as distinct from the protection of individuals. EPA proposes that the restrictions and clarifications provided in the methodology adequately address this concern given the current extent of knowledge regarding population dynamics. EPA requests comments on other approaches which may address the recommendation received from EPA's SAB.

4. Use of an Acute to Chronic Conversion Ratio

Participants at the Workshop and the Committees of the Initiative discussed the application of acute to chronic conversion ratios in the derivation of Tier I criteria. An acute/chronic ratio is applied to acute toxicity data (typically mortality) to estimate chronic effect levels. Workshop participants concluded that more data analysis of existing mammalian and avian acute and chronic toxicity data, possibly broken down by class of compound or mode of action, was needed to adequately define the empirical relationship between acute endpoints (e.g., LD50, the lethal dosage causing death in 50 percent of the exposed animals) and chronic endpoints (e.g., NOAEL, the highest tested dosage causing no observed adverse effect). Workshop participants recognized that before the use of acute/chronic ratios could be scientifically defensible, additional toxicity data might be needed. Given the current limited database, there was concern that the factor for extrapolating from acute data to chronic data would have to be so large that it would result in criteria or values which could be overly conservative. Therefore, EPA is proposing not to incorporate the use of an acute-to-chronic conversion factor in the Tier I methodology. EPA is also proposing that Tier II values not be based solely on acute toxicity data, instead requiring the use of subchronic or chronic data to derive an effect value. EPA invites comments on these proposed decisions.

D. Chemical Selection for Wildlife Criteria Derivation

The types of chemicals for which wildlife criteria should be developed under the GLWQI were addressed by the Workshop. These are: those which bioaccumulate (because wildlife species occupy higher levels in the trophic structure of a food web and, therefore, have a higher exposure); and those which have a unique metabolic pathway or mode of action which may make birds or mammals more sensitive toxicologically. The Committees of the Initiative agreed with the proposals of the Workshop that chemicals BAF greater than 250 should receive top priority for derivation of wildlife criteria. In addition, chemicals with BAFs less than 250 where wildlife impacts are suspected (e.g., lead) were included in the top priority list.

The Initiative Committees also identified nonpersistent, multiple application biocides (such as triazine herbicides and carbamates) are another group of chemicals for which wildlife criteria may be derived. These chemicals, although they are highly degradable and, therefore, have low bioaccumulation factors, are known to have detrimental effects on wildlife.

EPA agrees that the chemicals described above are those that most warrant the development of wildlife criteria and values. EPA is not requiring the Great Lakes States or Tribes to develop values for all of these chemicals, nor is EPA prohibiting any State or Tribe from addressing other chemicals if it believes that those other chemicals are causing adverse impacts on wildlife. EPA merely recommends that States or Tribes place a high priority on developing wildlife values for the chemicals identified by the Committees. EPA also intends to focus any future efforts to develop additional Tier I criteria for wildlife on these same chemicals of concern.

E. Tier I Wildlife Criteria and Tier II Wildlife Values

In the proposed Guidance, there are four chemicals for which Tier I wildlife criteria are proposed. These are mercury, PCBs, 2,3,7,8–TCDD, and DDT and metabolites. Only four wildlife criteria are being proposed for two major reasons: field studies from the Great Lakes indicate that the four pollutants for which wildlife criteria are proposed have had the most severe impacts on wildlife within the Great Lakes; and the criteria proposed are the first set of criteria for wildlife that EPA has ever developed. EPA cannot take advantage of an established and peer-reviewed National methodology to develop National wildlife criteria as it can for both human health and aquatic life criteria. The Initiative Committees and EPA lacked time and resources to develop additional numeric criteria for wildlife prior to this proposal. The State of Wisconsin had already identified these four chemicals as chemicals of concern for wildlife impacts in their State and completed literature reviews for these four chemicals. These literature reviews were updated as part of the GLWQI effort. The proposed numerical criteria are presented in Table VI–1. For additional information, EPA refers readers to the proposed methodology in appendix D to part 132, the Technical Support Document located in the appendix to this preamble, and the individual criteria documents available in the administrative record for this rulemaking. No Tier II wildlife values were calculated for inclusion in the proposed Guidance.

TABLE VI–1.—GREAT LAKES TIER I WILDLIFE CRITERIA

Chemical	Criteria (pg/L)
p,p'-dichloro- diphenyltrichloro-ethane (DDT) and Metabolites	0.87
Mercury (including Methylmercury)	100
Polychlorinated biphenyls (PCBs)	17
2,3,7,8-tetrachlorodibenzo-p-dioxin (2,3,7,8–TCDD)	0.0096

F. Comparison With the CWA and Relationship to National Guidance

The observed effects on wildlife species in the Great Lakes basin are clear evidence that the Clean Water Act (CWA) goals of protecting the biological integrity of the Nation's waters and attaining water quality which provides for the protection of wildlife are not being met in the Great Lakes (see 33 U.S.C. 1251(a)).

1. Relationship to Existing National Guidance

Currently, there exists no National guidance for wildlife protection comparable to the proposed Guidance. However, there is a mechanism for consideration of wildlife impacts within the 1985 National aquatic life criteria guidelines (Stephan, et al., 1985). In those guidelines, if a maximum permissible tissue concentration is available from a maximum acceptable dietary intake based on observations on survival, growth, or reproduction in: A chronic wildlife feeding study; or a long-term wildlife field study, or from an FDA Action Level, a Final Residue Value can be calculated. This Final Residue Value is calculated by dividing maximum permissible tissue concentrations by appropriate lipid-normalized bioconcentration or bioaccumulation factors.

This methodology provides a mechanism to protect against bioaccumulation of a compound within a food web. However, it also has limitations. A Final Residue Value derived using an FDA Action Level does

not ensure protection of wildlife species which may consume contaminated aquatic organisms as a larger portion of their diet or exhibit a greater sensitivity than the human which the FDA Action Level is derived to protect. If no maximum permissible tissue concentration is available, no Final Residue Value is calculated and, therefore, biomagnification of a chemical into the higher trophic levels of a food web, and potential impacts on these wildlife species, is not considered in the derivation of the Aquatic Life Criterion.

EPA's current National aquatic life criteria for DDT and PCBs are based on wildlife toxicity information (U.S. EPA, 1980 a and c, respectively). Wildlife toxicity data was also considered in the derivation of the current aquatic life criterion for mercury (U.S. EPA, 1980b). For both DDT and PCBs, a bioconcentration factor (BCF) rather than a bioaccumulation factor was used in the derivation of these aquatic life criteria. In both cases, the BCF was known to underestimate the bioaccumulative potential of the compound, and in the PCB Aquatic Life Criteria document (U.S. EPA, 1980c), underestimating the bioaccumulative potential was identified as leading to a criterion which may be underprotective of wildlife species at risk.

EPA has begun a separate effort to derive National wildlife criteria. Following the release of the 1987 General Accounting Office report entitled "National Refuge Contamination is Difficult to Confirm and Clean Up," (GAO, 1987), EPA began to work cooperatively with U.S. Fish and Wildlife Service to develop methods for deriving National wildlife criteria. The wildlife criteria efforts carried out within the Great Lakes Water Quality Initiative have been coordinated with the on-going National efforts. However, within the development of National wildlife criteria, wildlife are defined as mammals, birds, reptiles and amphibians. This broader definition of wildlife was considered in the early stages of wildlife criteria development for the GLWQI. However, the decision was made to move forward with wildlife criteria considerate of impacts on mammals and birds at this time because of the lack of chronic or sub-chronic toxicological data for reptiles and amphibians. The incorporation of effects on reptiles and amphibians is also complicated by the significance of, and lack of data for, the dermal route of exposure to reptiles and amphibians. EPA requests recommendations on how reptiles and amphibians can be incorporated into the proposed GLWQI methodology or suggestions for an alternative wildlife criteria methodology considerate of impacts on reptiles and amphibians.

2. Relationship to Current Efforts To Provide National Guidance for the Development of Wildlife Criteria

There are efforts underway within EPA to develop guidance for National wildlife criteria. The proposed Guidance is being considered as one alternative which might be modified for nationwide use. The Great Lakes Guidance has as its focus the protection of wildlife populations inhabiting the Great Lakes basin. Although National guidance may eventually be modeled on the proposed Guidance, it should not be expected that the National guidance would result in identical criteria. EPA invites comments on the modification of this approach for development of a National wildlife criteria procedure.

G. Comparison of Wildlife Criteria and Methods to National Program and to Great Lakes Water Quality Agreement

1. "No Less Restrictive" Than the CWA and National Guidance

Since the current National guidance contains no method for calculating criteria for the sole protection of wildlife and no values based solely on the protection of wildlife, a direct comparison is difficult. The National guidance allows some consideration of wildlife impacts in the calculation of criteria for aquatic life. Current National criteria for aquatic life can be compared with the proposed criteria for wildlife, although the comparison may not be especially meaningful. All four of the Tier I criteria for wildlife proposed are, in fact, more restrictive than the existing aquatic life standards for the same pollutants. Since the new wildlife criteria will apply in almost all Great Lakes waters, they will in a rough sense provide more protection than the National guidance.

As explained in section B above, in the discussion of aquatic life criteria, Tier II values will almost always be more restrictive than both new Great Lakes Tier I criteria and existing National criteria. Hence, EPA believes that future Tier II wildlife values generally will not be less restrictive than the National program.

2. Conformance With the Great Lakes Water Quality Agreement

As explained above in the discussion of aquatic life criteria, EPA does not believe that Congress intended to require EPA to adopt criteria identical to the specific numerical limits set out as "Specific Objectives" in Annex 1 of the Great Lakes Water Quality Agreement (GLWQA). In addition, only five of these "Objectives" focus on the protection of wildlife. EPA notes that the proposed wildlife criterion that can be most readily compared to a wildlife limit in the GLWQA is more restrictive than the GLWQA's limit. EPA is proposing a wildlife criteria for DDT of 0.87 pg/L. The GLWQA's Annex 1 limit for DDT is 3.0 pg/L.

Finally, as discussed above, EPA intends to try to revise the GLWQA to replace existing Annex 1 limits with the new criteria proposed.

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VII. Antidegradation

A. General Discussion/Background

Today's **Federal Register** notice proposes guidance to be followed by the Great Lakes States and Tribes in the development of antidegradation policies and implementation procedures for the waters of each State that are within the Great Lakes System. Antidegradation policies and implementation procedures are mechanisms that can be used by EPA and the States to protect the water quality of the Nation's surface waters and to maintain improvements that have been made in that quality.

The Federal regulations at 40 CFR 131.12 set out the Federal antidegradation policy and require that each State develop and adopt a policy and methods for implementing that policy that, as a minimum, are consistent with the requirements set forth in the Federal policy. Furthermore, the regulations at 40 CFR 131.6 require each State to include such an antidegradation policy as one of the elements of the State's water quality standards submittal.

Each Great Lakes State has adopted an antidegradation policy that EPA has determined satisfies the minimum requirements of the above Federal regulations. However, the policies and implementation procedures adopted by the States vary considerably in form and specificity, and EPA and the Great Lakes States share concern that there exists great potential for inconsistent antidegradation decisions to arise as a result of these differences. EPA and the Great Lakes States agreed at the outset of the Initiative that one of the outputs of the process should be antidegradation policy and implementation procedure guidance. Each Great Lakes State would follow the resulting guidance when revising its water quality standards, with the intended result being greater consistency among State policies and procedures. The passage of the Great Lakes Critical Programs Act of 1990 (CPA) made the development of this Great Lakes antidegradation guidance mandatory.

In September 1991, the States of Michigan, Minnesota, and Wisconsin, the Province of Ontario, the Government of Canada, and EPA entered into an agreement entitled "A Bi-National Program to Restore and Protect the Lake Superior Basin." Among the elements in this agreement are enhanced antidegradation requirements for areas of the Lake Superior Basin given special protection designation by the three States. This proposed Guidance includes special antidegradation requirements applicable to those areas of the Lake, upon designation by a State or States.

The following discussion briefly summarizes the history of the Federal policy and outlines both the Federal policy and that developed for the proposed Guidance. It also provides a detailed overview of the requirements of the antidegradation policy contained in the proposed Guidance, which includes an antidegradation standard, antidegradation implementation procedures, antidegradation demonstration requirements, and antidegradation decision requirements. Unique characteristics and requirements of the Great Lakes System and their effect on the proposed Guidance, as well as specific issues that arose during consideration of the options for the proposed Guidance and their resolution, are discussed. Finally, throughout the discussion, EPA has identified specific issues for which it is seeking comment to aid in the development of the final Guidance.

1. Federal Antidegradation Policy and History

a. *History of the Federal Antidegradation Policy.* The Federal antidegradation policy has its roots in the Water Quality Act of 1965 (Pub. L. 89–234), which stated in its declaration of policy, "The purpose of this Act is to enhance the quality and value of our water resources and to establish national policy for the prevention, control, and abatement of water pollution."

Policy guidelines established by the Department of the Interior in 1966 for use in the approval of States' water quality standards contained additional direction on antidegradation, stating that "In no case will standards providing for less than existing quality be acceptable" and "The water quality standards proposed by a state should provide for: * * * The maintenance and protection of quality and use or uses of waters now of a high quality or of a quality suitable for present and potential future uses." Secretary of the Interior Udall further defined the Federal policy on antidegradation in 1968, when he said that each State was to include a statement similar to the following in their water quality standards:

> Waters-whose existing quality is better than the established standards as of the date on which such standards become effective will be maintained at their existing high quality. These and other waters of a State will not be lowered in water quality unless and until it has been affirmatively demonstrated to the State water pollution control agency and the Department of the Interior that such change is justifiable as a result of necessary economic or social development and will not interfere with or become injurious to any assigned uses made of, or presently possible in, such waters. This will require that any industrial, public or private project or development which would constitute a new source of pollution or an increased source of pollution to high quality waters will be required, as part of the initial project design, to provide the highest and best degree of waste treatment available under existing technology, and, since these are also Federal standards, these waste treatment requirements will be developed cooperatively.

The Federal Water Pollution Control Act Amendments of 1972 (Pub. L. 92–500) continued to emphasize the prevention of pollution and, in 1973, EPA developed guidance for State water quality standards under the Amendments that essentially repeated the 1968 statements of Secretary Udall.

In 1975, EPA promulgated regulations at 40 CFR 130.17(e) that required the States to develop an antidegradation policy and implementation procedures. The 1975 rule contained provisions that are very similar to those in 40 CFR 131.12, and provided protections for existing uses, high quality waters, high quality waters that constituted an outstanding National resource, and waters impaired by thermal discharges. To summarize, the 1975 rule required that:

i. Existing in-stream water uses must be maintained and protected and that no degradation that would interfere with or become injurious to existing in-stream uses could be allowed;

ii. High quality waters (those in which the water quality exceeds that necessary to support propagation of fish, shellfish and wildlife and recreation in and on the water) must be maintained and protected unless the state chooses, after public participation and intergovernmental coordination, "to allow lower water quality as a result of necessary and justifiable economic or social development," and provided that the degradation does not interfere with or become injurious to existing uses and that the highest statutory and regulatory requirements for point sources and feasible management practices for nonpoint sources are achieved;

iii. High quality waters that constitute an outstanding National resource must not be degraded; and

iv. Where the potential for water quality impairment involved a thermal

discharge, antidegradation policy and implementation must be consistent with section 316 of the Clean Water Act.

Citing the longstanding debate over the impact of the antidegradation policy on economic growth, EPA proposed to change and significantly restrict the effect of the policy in 1982. In proposed water quality standards rules published in the **Federal Register** on October 29, 1982 (47 FR 49234), EPA proposed a new antidegradation policy and took comment on two alternative approaches. The proposal would have created a new 40 CFR 131.10(c) which stated, "States must develop and adopt a statewide antidegradation policy to maintain existing water uses." As stated in the preamble (47 FR 49238–49239), the proposed regulation was "based on limiting the mandatory antidegradation policy to the protection and maintenance of existing uses." The preamble further stated that "the emphasis in this proposal is on the use, not the individual water quality parameters which might, in any particular water body, be higher than necessary to protect the existing use." The proposal eliminated special protections for high quality waters and Outstanding National Resource Waters, but required that existing uses be maintained regardless of future growth or development that might affect water quality.

One option, put out for comment in the 1982 proposal, retained the existing (1975) antidegradation policy, except that it eliminated the provisions related to outstanding National resource waters because the Clean Water Act did not provide for such special designations of National resource waters. EPA did note, however, that the States were free under section 510 of the Clean Water Act to make such designations in their water quality standards.

Another option for public comment in the 1982 proposal would have let the States remove existing uses if their protection and maintenance would have effectively prevented future growth, or if the benefits of maintaining an existing use were outweighed by its costs. Removal of an existing use would have required full public participation and would not have relieved any of the Clean Water Act minimum technology requirements for point sources.

The extensive public comment on the 1982 proposal favored retaining the existing (1975) antidegradation policy over any of the alternatives. In response, EPA issued final rules on November 8, 1983 (48 FR 51400) that retained, with certain changes, the 1975 antidegradation policy and incorporated it into the regulations at 40 CFR 131.12. The changes to the 1975 antidegradation policy are discussed in the preamble to the 1983 rulemaking (48 FR 51402–51403), but they were generally intended to clarify the policy with no change in coverage or effect. An exception to this was the change in the provisions applicable to outstanding National resource waters, which eliminated the strict "no degradation" requirement in favor of a limited exception for activities that result in temporary and short-term lowering of water quality. The resulting National antidegradation policy is discussed in detail below under the heading Existing National Antidegradation Policy.

Finally, the 1987 Water Quality Act Amendments to the Clean Water Act (CWA) explicitly incorporated reference to antidegradation policies in section 303(d)(4)(B), which requires that such antidegradation requirements be satisfied prior to modifying certain NPDES permits to include less stringent effluent limitations.

In addition, the Governments of Canada and the United States have entered into the Great Lakes Water Quality Agreement of 1978 (GLWQA), which also requires a strong antidegradation process for its objectives to be fully realized. The purpose of the GLWQA is to restore and maintain the chemical, physical and biological integrity of the waters of the Great Lakes Basin Ecosystem. In order to achieve this purpose, the two Governments have agreed to eliminate and reduce to the maximum extent practicable the discharge of pollutants into the Great Lakes System. Both Governments have established policy under the GLWQA that the discharge of toxic substances in toxic amounts be prohibited and that the discharge of any or all persistent toxic substances be virtually eliminated. Finally, a Specific Objective of the GLWQA is for all reasonable and practicable measures to be taken to maintain and improve the existing water quality in those areas where such water quality is better than that prescribed by Specific Objectives and in those areas having outstanding natural resource value.

On November 16, 1990, Congress amended section 118 of the Clean Water Act with the CPA. The CPA requires that EPA develop a proposed and final Guidance, including antidegradation policies, and publish it in the **Federal Register**. The Guidance must conform with the objectives and provisions of the GLWQA and be no less restrictive than the provisions of the Clean Water Act and National guidance. States are required to adopt into rules water quality standards, antidegradation policies, and implementation procedures which are consistent with the proposed Guidance. If a Great Lakes State fails to adopt such standards, policies and procedures, EPA is required to promulgate the Guidance for that State.

b. *Existing National Antidegradation Policy.* EPA has defined a "tiered" antidegradation approach for the protection and maintenance of water quality based on the existing quality of the water. The Federal antidegradation policy at 40 CFR 131.12 establishes three tiers of restrictions on the lowering of water quality, and a fourth requirement applicable to thermal discharges.

The first tier, applicable to all waters, is established by 40 CFR 131.12(a)(1), which requires that all existing uses of the water body and the level of water quality necessary to protect those uses be maintained and protected. EPA interprets this to mean that water quality in any water body may be lowered only to the point at which the water quality is sufficient to protect and maintain all existing uses, and that it is not permissible to allow water quality to be lowered to the extent that any existing use is impaired. The 1983 Water Quality Standards Regulation preamble described this provision as the "absolute floor of water quality in all waters of the United States" (48 FR 51400, 51403, November 8, 1983). Note also that other parts of the water quality standards regulation provide that States must adopt water quality criteria sufficient to protect all designated uses, and that designated uses must include existing uses. Certain decisions regarding the lowering of water quality, such as those involving NPDES permitted discharges, must also ensure that the criteria applicable to such designated uses are achieved, whether or not the designated use is an existing use.

The second tier is established by 40 CFR 131.12(a)(2), which provides protection of actual water quality in water bodies that support the propagation of fish, shellfish, wildlife and recreation in and on the water ("fishable/swimmable"). Waters, the quality of which exceeds that necessary for fishable/swimmable, are termed high quality waters (HQWs). Under 40 CFR 131.12(a)(2), limited degradation of such waters may be allowable if necessary for important social and economic development in the areas in which the waters are located, but only after public involvement and only as long as the water quality remains adequate to be "fishable/swimmable." The process for determining whether the lowering of

water quality is necessary to accommodate important social and economic development is referred to as the antidegradation demonstration and decision.

The third tier (40 CFR 131.12(a)(3)) affords special protection to waters that have been designated Outstanding National Resource Waters (ONRWs) by the States. The water quality in ONRWs must be maintained and protected. The preamble discussion in the 1983 Water Quality Standards Regulation cited above indicates that EPA did not intend for this to be an absolute prohibition on any lowering of water quality in ONRWs. It allows States some limited activities which result in temporary and short-term changes in water quality.

The final provision (40 CFR 131.12(a)(4)) requires that the State antidegradation policy and implementation procedures be consistent with section 316 of the Clean Water Act as regards lowering of water quality involving thermal discharges. This recognizes that thermal variances granted under section 316 can override otherwise applicable water quality standards, including antidegradation standards.

EPA has developed a variety of guidance materials to assist the States in the development of their antidegradation policies and implementation procedures, and to aid EPA in the review of such policies and procedures (e.g., Water Quality Standards Handbook (1983)), which is available in the administrative record for this rulemaking.

c. *Great Lakes States Experience.* The Great Lakes antidegradation policy contains several requirements that draw from the collective experience of the Great Lakes States and EPA in studying, managing and protecting the Great Lakes System. The unique character of the Great Lakes System and the problems it faces are a major impetus behind the Initiative in general, and the basis for several of the specific requirements in the Great Lakes antidegradation policy.

Because of the long retention time and the complex flow patterns of the water in the Great Lakes System, the Lakes tend to act as a sink, accumulating pollutants discharged to them. There is an identified problem in the Great Lakes associated with substances that are highly bioaccumulative in the tissues of aquatic organisms. Contamination by such substances has resulted in State-imposed fish consumption advisories and restrictions for humans, and has been implicated in a variety of adverse biological effects, such as impaired reproductive success and deformities, among aquatic organisms and the wildlife that consume them. A special emphasis is made in the proposed Guidance to restrict increases in the rate of loading of highly bioaccumulative chemicals. Such "bioaccumulative chemicals of concern" (BCCs) are those with a bioaccumulation factor of 1000 or greater, determined using the GLWQI BAF procedures. The BAF procedures are found in appendix B and the list of BCCs are found in Table 6 of section 132.4 of the proposed Guidance. BCCs are discussed in detail and comments are invited in section I.A of the preamble.

As discussed in detail below, under C.2 "Significant Lowering of Water Quality", the Tier II protections in the proposed Guidance for high quality waters are focussed on actions that have the potential to significantly lower water quality.

The unique character and importance of the Lake Superior Basin is also reflected in the proposed Guidance. Provisions are included for special protection of waters designated Lake Superior—Outstanding International Resource Waters or Lake Superior Basin—Outstanding National Resource Waters by the States. These are discussed below under Special Antidegradation Provisions for Lake Superior.

The Great Lakes priorities should not be interpreted as EPA's priorities for water bodies nationwide. EPA expects the significant lowering of water quality to be potentially different in other areas depending on the priority concerns identified through water quality management planning processes.

d. *Alternative Approaches to Assessing Lowering of Water Quality.* The Federal antidegradation policy, and the proposed Great Lakes antidegradation policy, apply to actions that lower water quality. Typically, water quality is considered to be lowered when the concentration of a pollutant in the water is increased, or the concentration of a necessary substance such as dissolved oxygen is decreased. In developing the proposed guidance EPA and the Great Lakes States considered several alternative approaches that could be used to assess whether an action would potentially lower water quality.

One approach that could be used to determine if water quality was lowered would rely on sampling and analysis of the water body to determine if any measurable change occurred in the concentration of a pollutant or pollutants. EPA and the Great Lakes States considered such an approach during the development of the proposed Guidance. This approach has the advantage that it actually uses information about the ambient levels of pollutants to determine if a change in water quality occurs. The approach is not proposed in the proposed Guidance, however, because many of the pollutants about which the Great Lakes States and EPA are most concerned cause adverse effects in the Lakes at concentrations that cannot be measured in the ambient water using readily available analytical techniques. Furthermore, EPA and the Great Lakes States are concerned about the potential difficulty a regulatory agency would face in linking the actions of a specific source of the pollutant to the measured change in ambient water quality. Finally EPA is very concerned that such an approach is contrary to the intent and plain text of the Federal antidegradation regulation. In particular, 40 CFR 131.12(a)(2) requires that water quality be maintained and protected unless a State finds that the lowering of water quality is necessary to accommodate important social and economic development. This clearly necessitates an affirmative finding by the State before a water quality can be lowered, not after it has been measured.

Another approach that could be used to determine whether an action could lower water quality would look at the amount of pollutant released into the water. Working from the premise that, all other things being equal, a change in the amount of a pollutant added to a water body will result in a change in the concentration of that pollutant in the water body, such an approach would look at changes in the mass loading rate of a pollutant or pollutants as being potential indicators of changes in water quality. EPA and the Great Lakes States considered several alternatives that would implement such an approach. All of the alternatives that derive from this approach would require prior approval of a change in the loading of a pollutant if that change lowered water quality or was projected to lower water quality. Where the alternatives differ is in the threshold at which water quality is determined to be lowered and the flexibility provided the regulatory agency in making such a determination.

One alternative EPA and the Great Lakes States considered would define the lowering of water quality in terms of a projected increase in the ambient concentration of a pollutant. This alternative would use models (simple mass balance or more sophisticated dynamic models if appropriate) to project the effect of a change in the mass loading rate of a pollutant or pollutants on water quality, generally focussing on

changes in effluent limitations and wasteload allocations. This is the way in which antidegradation policy has typically been implemented in the past.

A second alternative EPA and the Great Lakes States considered would define any increase in the rate of mass loading of a pollutant as lowering water quality. This alternative was appealing to EPA and the Great Lakes States because the Great Lakes tend to act as a sink for many pollutants and there was a concern that the models used in the first alternative would not be protective for persistent pollutants that might accumulate in the Lakes.

A third alternative considered for the proposed Guidance is a hybrid of the first two. To account for the concerns with the BCCs, the proposed Guidance would consider the lowering of water quality to occur whenever the rate of mass loading of these pollutants (BCCs) from an individual point or nonpoint source increases. For the remaining pollutants (the non-BCCs), any increase in an existing limitation beyond a de minimis change would be considered an action that would lower water quality sufficiently to require an antidegradation review. This approach would focus regulatory attention on the pollutants of primary concern—the BCCs—and, for the remaining (non-BCC) pollutants, use information on the effect of the proposed action on ambient water quality in determining the need for an antidegradation determination. EPA and the Great Lakes States settled on such a hybrid alternative and it is embodied in the definition of significant lowering of water quality in the proposed Guidance.

The sections that follow set out in detail the basic elements of the proposed approach and discuss some alternatives for each of these elements. EPA requests comments on all of the alternative approaches identified above. In providing comments, EPA is particularly interested in information on the relative effectiveness of these alternative approaches in meeting water quality goals, the difficulties and advantages of their implementation, and their likely costs. EPA is also interested in comments on the effect of requiring prior approval, through the antidegradation process proposed in this Guidance, of actions such as discharge increases that have the potential to lower water quality. EPA recognizes that delays in business decisions, such as production rate increases in response to market changes, might result because the attendant pollutant loading rate increases would require prior approval. As a result of the requirement for loading limits in the implementation procedures proposed today, and the focus on loading rates of the BCC pollutants, EPA believes that a larger number of actions may be subject to antidegradation review and prior approval requirements than under existing policy. The potential costs that might be associated with decreased flexibility to respond to market changes could, therefore, also be greater than under existing policy, EPA has no data from which to estimate the potential costs that might be associated with decreased flexibility to respond to market changes; However, EPA is interested in any such information that commenters are able to provide.

The definition of significant lower of water quality reflects the unique characteristics of the Great Lakes System (as described below). Actions or decisions that have the potential to significantly lower water quality include those that might result in any increase in the actual rate of mass loading of a BCC and those that require an increase in an existing limitation for any other pollutant. EPA is also interested in comments though, on whether the definition of significant lowering of water quality should distinguish between BCCs and other chemicals. In particular, EPA is interested in whether BCCs would be adequately controlled if the same definition of significant lowering of water quality as is applied to other chemicals were to be used for BCCs. Such an approach would have the effect of tying the definition of significant lowering of water quality for all pollutants to increases in permit limits. It would provide opportunity for a de minimis demonstration for increases in limitations on BCCs. It would also provide opportunity for an entity to attempt to demonstrate that the ambient concentration of the BCC would not increase. EPA also welcomes suggestions regarding any changes or specific requirements that should be made or added to the de minimis test and the demonstration of no ambient change to address BCCs if the definition of significant lowering of water quality were to be changed as discussed above. EPA invites comment on these approaches and suggestions for others that should be considered.

B. General Outline of GLWQI Antidegradation Process

1. Narrative Flow Chart of Process

As previously noted, the CPA mandates that the EPA publish, among other things, an antidegradation policy. The Great Lakes antidegradation policy proposed in the proposed Guidance is comprised of the following four components: antidegradation standard, antidegradation implementation procedures, antidegradation demonstration, and antidegradation decision. The policy is constructed as a model regulation in the following sequence.

The "Antidegradation Standard" is a statement of the general requirements with regard to maintenance and protection of water quality in the Great Lakes System. It is generally the same as the National regulation. Additionally, it clarifies that the lowering of water quality is to be considered and evaluated on a pollutant-specific basis.

The "Antidegradation Implementation Procedures" define the procedures to be used by the Great Lakes States and Tribes to implement the general Standard. Appendix E, sections II.B through D, establish tiered procedures, specific to the quality of the water in question, which track the tiered approach of the Standard. The procedures identify priorities of the Great Lakes States and Tribes with regard to BCCs and define situations in which the lowering of water quality in HQWs will be considered significant and subject to a detailed antidegradation demonstration review pursuant to this proposed Guidance. Appendix E, section II.D, specifically addresses maintenance of water quality in HQWs with respect to bioaccumulative chemicals of concern and other pollutants. This section also identifies special designations available for Lake Superior and defines the procedures and restrictions applicable to areas of the Lake so designated.

The "Antidegradation Demonstration" defines the information that an entity that is seeking to significantly lower water quality in a high quality water must provide in support of that request. It promotes pollution prevention and requires that entities develop information regarding the costs associated with the use of alternative or enhanced treatment that would eliminate the lowering of water quality. This section also identifies information that must be provided by any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern (BSIC) to a Lake Superior Outstanding International Resource Water.

The "Antidegradation Decision" identifies the process that the State or Tribe will follow in evaluating the information provided in the antidegradation demonstration and in reaching a decision on the significant lowering of water quality. The proposed

Guidance directs the State or Tribe to require the entity to implement prudent and feasible pollution prevention alternatives that reduce the extent of, or eliminate, the lowering of water quality. It also identifies minimum expenditures for alternative or enhanced treatment that will be required of an entity if the treatment eliminates the lowering of water quality. It further requires that the State or Tribe consider the social and economic benefits in light of the environmental effects associated with the lowering of water quality in order to reach the decision. The State or Tribe may either conduct a full review of the technical merit of the demonstration and make its tentative decision accordingly, or alternatively, the State or Tribe may choose to determine that the administrative requirements of section VII. B.1.c of the preamble, have been met and solicit public comment prior to such a technical review. In the latter instance, the tentative decision of the State or Tribe shall be, as a matter of policy, to propose that existing water quality be maintained and protected.

The Antidegradation Implementation Procedures place requirements on the decision-making of the Federal, State and local regulatory agencies as they consider actions proposed by a regulated entity, whether involving a point or nonpoint source, that have the potential to lower water quality beyond a specific threshold. (Note that throughout the Policy, the term "Director" is used to signify the decision-maker in the regulatory agency.) For all tier 1 waters where water quality for a particular pollutant or pollutants does not exceed that required to maintain the designated uses and the existing uses, the threshold is any lowering of water quality, as signified by any increase in the rate of mass loading of the pollutant or pollutants to the water. In such waters, no increase in the rate of mass loading of any such pollutant is allowable, so the procedures direct the regulatory agencies to write control requirements, such as NPDES permit limitations, that at a minimum will prevent increases in the rate of mass loading of the pollutant or pollutants of concern. For outstanding National resource waters (tier 3), the threshold is any lowering of water quality for any pollutant. In such waters, no increase in the rate of mass loading of any pollutant is allowable, so the procedures direct the regulatory agencies to write control requirements, such as NPDES permit limitations, that at a minimum will prevent increases in the rate of mass loading of all pollutants. For HQWs (tier 2), the threshold is any significant lowering of water quality, a term which is defined in the proposed Guidance and discussed later in this preamble. For Lake Superior Basin waters provided special protection designation by a State or States, the proposed Guidance describes specific restrictions on the lowering of water quality by any of nine listed Lake Superior bioaccumulative substances of immediate concern (BSICs). (The Bi-National Program to Restore and Protect the Lake Superior Basin identifies two special protection designations that might be adopted by the States. The first such designation, a Lake Superior Basin—Outstanding National Resource Water, is an area within the basin so designated by a State for the purpose of preventing new or increased discharges of BSICs from point sources. The second, Outstanding International Resource Water, exists if the States (Michigan, Minnesota and Wisconsin) so designate the Lake Superior Basin, and has the effect of preventing the new or increased discharge of BSICs until an adequate antidegradation demonstration, which includes the installation of the best technology in process and treatment, is accomplished.) For substances other than the BSICs, the Lake Superior special protection designations have no direct effect, and such substances are treated the same as in the remainder of the Great Lakes System.

Proposed actions that have the potential to significantly lower water quality in HQWs must be evaluated by the regulatory agency to determine if they are necessary to accommodate important economic and social development in the area in which the waters are located. To guide the regulatory agency in making this determination, the proposed Guidance establishes two tests: one that demonstrates that the significant lowering of water quality is necessary, i.e., the lowering of water quality cannot be prevented through the use of prudent and feasible pollution prevention techniques, or alternative or enhanced treatment techniques that are available within a specified cost range; and a second, subsequent test that is used to establish that the action significantly lowering water quality will accommodate important economic and social development in the area in which the waters are located.

The proposed Guidance identifies five categories of pollution prevention alternatives that must be evaluated: substitution of BCCs with other nonbioaccumulative and nontoxic chemicals; application of water conservation methods; waste source reductions within process streams; recycle and reuse of waste byproducts; and manufacturing process operational changes. In addition, the Director may add categories of pollution prevention alternatives which are applicable to specific situations. For instance, the alternative of scaling down the amount of fill might be appropriate in a section 404 permit action. The proposed Guidance requires that the entity proposing the action supply to the regulatory agency information on the alternatives available, their effectiveness, and costs, along with any other information the agency might require to determine if specific alternatives alone or in combination are prudent and feasible. The Director will require the entity to implement alternatives that are determined to be prudent and feasible and will establish control requirements that reflect the implementation of such alternatives. The implementation of prudent and feasible pollution prevention alternatives need not entirely eliminate the significant lowering of water quality for them to be required by the Director. Unlike the alternative or enhanced treatment provision discussed below, prudent and feasible pollution prevention alternatives are to be required whenever they are effective at reducing the degree to which water quality would be significantly lowered by an action.

The proposed Guidance also identifies benchmarks to be applied by the regulatory agency in determining if alternative or enhanced treatment techniques should be required, in addition to prudent and feasible pollution prevention alternatives, to eliminate the lowering of water quality that would otherwise result from an action. The proposed Guidance directs the entity proposing the action to identify for review by the regulatory agency any alternative or enhanced treatment techniques available that would, in conjunction with the implementation of prudent and feasible pollution prevention alternatives, eliminate the need to significantly lower water quality, along with the associated capital and operation and maintenance costs. In addition, the entity must provide comparable information on the capital and operation and maintenance costs associated with pollution control facilities necessary to achieve compliance with applicable Federal effluent guidelines-based or water quality-based effluent limitations. The proposed Guidance directs the regulatory agency to require the implementation of such alternative or

enhanced treatment techniques that are available at a cost ratio of 1.1 to one (alternative or enhanced treatment compared to that otherwise required).

If, after the above evaluations and implementation of the prudent and feasible pollution prevention alternative or alternatives, the proposed action will continue to significantly lower water quality, then the action must be evaluated by the regulatory agency to establish that the significant lowering of water quality will accommodate important economic or social development in the area in which the waters are located. The proposed Guidance requires that the entity proposing the action identify developments, falling in any of the following categories, that will be foregone if the significant lowering of water quality is not allowed: increase in the number of jobs; increase in personal income or wages; reduction in the unemployment rate or other social service expenses; increase in tax revenues; or provision of necessary social services. No benchmarks are specified for the evaluation of the social and economic developments; rather the regulatory agency is provided the flexibility to fit the analysis to the condition of the community and area involved. Nonetheless, the action should have some positive developmental effect in one or more of the categories listed above or the lowering of water quality should not be approved by the regulatory agency. Furthermore, the proposed Guidance provides for a review by the Director of information on the environmental effects of the action, after required pollution prevention/control alternatives are implemented. Such environmental effects would not be limited to the water media; the information could be used by the regulatory agency to account for cross-media effects in making the final decision.

The proposed Guidance provides two options to the regulatory agency on the draft decision regarding the lowering of water quality, which vary depending on how the agency decides to complete the review of the social and economic developments. The agency may wish to conduct a full review of the merit of the action and make its tentative decision accordingly, in which case it would public notice the resulting proposed decision and the basis for the decision. Alternatively, the agency may wish to take public comment on the action and associated social and economic developments before it renders a decision based on its review of the merits of the antidegradation demonstration. In this case, the agency would public notice a tentative decision to maintain and protect water quality (i.e., reject the significant lowering of water quality). The public notice would include for public review and comment the antidegradation demonstration provided by the entity proposing the action, along with the agency's determination that the demonstration is administratively complete. The notice would furthermore indicate that the agency had deferred its decision on allowing a lowering of water quality pending review of the public comment, and that the tentative decision to maintain and protect water quality may be revised based on public comment and the agency's review of the full antidegradation demonstration.

2. Preconditions for Implementation of Antidegradation Procedures

Several other ongoing water quality management planning processes are integral to antidegradation implementation, and for the purpose of this procedure are expected to be implemented correctly as preconditions to antidegradation review of any proposed action that could significantly lower ambient water quality. Deficiencies in these underlying programs should be corrected before any activity is considered that could significantly lower water quality.

At the onset of the antidegradation review procedure, the water quality standards established for the receiving water body pursuant to 40 CFR 131 must be correct and appropriate. The term "water quality standards" as used here is defined at 40 CFR 131.3(i) and includes both the designated uses of the water body and the criteria that support the designated uses. Existing uses and, where attainable, fishable/swimmable uses are expected to be reflected in the use designation, and appropriate criteria to support those uses adopted. It is assumed that if the standards have undergone the triennial review process in the last three years and are approved by EPA, they are correct and appropriate.

The potential for an action to result in a significant lowering of water quality will be considered on a parameter-by-parameter basis. Unless the appropriate and established water quality standards have been achieved, there is no potential to allow an action that could lower water quality, subject to an antidegradation review, because there would be no remaining unused assimilative capacity. Water quality standard exceedances may be a result of any one or a combination of factors, including but not limited to: an inadequate total maximum daily load (TMDL), wasteload allocation (WLA), or load allocation (LA); uncontrolled sources; and point source dischargers that are not in compliance with their NPDES permits. Such water quality standards violations must be corrected prior to consideration of an increased loading of a pollutant from any source through the antidegradation review process. Further, if water quality standards are not being achieved, the State should establish a revised TMDL/WLA/LA; bring non-compliant dischargers into compliance with appropriate water quality-based effluent limitations; or, in some other way, correct the ambient water quality problem.

3. Steps Preceding an Antidegradation Review

a. *Establish That the Action May Significantly Lower Water Quality.* Prior to requiring an antidegradation demonstration and review the regulatory agency must establish that the proposed action results in, or may result in, a significant lowering of water quality. The definition of significant lowering of water quality differentiates between BCCs and other pollutants as follows (see section VII.C.2 of the preamble for a detailed discussion of the definition of significant lowering of water quality and its implications): Any increase from the baseline rate of mass loading of a BCC is significant lowering of water quality; and for pollutants other than BCCs, any increase in the permitted levels (or otherwise allowable mass loading rate) unless such an increase would have no effect, or a de minimis effect, on the receiving water, is significant lowering of water quality.

For point source discharges, examples would include an increased effluent load limit for a non-BCC in a reissued NPDES permit, where such an increase would have greater than a de minimis effect on the receiving water; or for BCCs, a deliberate action by a permittee, such as addition of a new production line, that would result in an increased mass loading rate of a BCC above the baseline loading rate for the pollutant as established in the permit.

As regards BCCs, when discussing NPDES permit issuance, at this point in the process the permit issuance authority will have defined the applicable "baseline" (i.e., the lowest of either the existing limit, the "new" technology-based effluent limit, the "new" water quality-based effluent limit, or existing effluent quality), and any increase from this "baseline" that is requested by the permittee. The mass loading rate will be restricted to this

baseline in the permit unless the permittee justifies the increase to the satisfaction of the permitting agency, after the opportunity for public input, through the antidegradation process set forth in the proposed Guidance. The baseline for a BCC could, however, be adjusted without an antidegradation demonstration to account for an increase in discharge volume that results in an increased rate of mass loading of a BCC pollutant due solely to the presence of that pollutant in the intake water.

Where independent regulatory authority requiring compliance with water quality standards already exists, other regulated actions that may result in an increased rate of mass loading of pollutants and, potentially, the significant lowering of water quality would also be subject to antidegradation review. Review of such proposed actions by the regulatory agency should determine whether the action has the potential to significantly lower water quality, and, if so, the action is required to go through the antidegradation process. Depending on Federal, State and Tribal authorities, such activities may include actions, such as changes in land use, which result in increased nonpoint pollutant runoff or removal of a riparian buffer strip which may allow increased agricultural runoff. Where there is regulatory authority requiring compliance with water quality standards, regulatory agencies permitting air emissions (subject to section 112(m) of the Clean Air Act or similar State authorities) should consider the potential for significant lowering of water quality, and if applicable, subjected to an antidegradation review. EPA does not intend through the proposed Guidance to require compliance with antidegradation provisions where independent regulatory authority requiring compliance with water quality standards does not already exist.

b. *Characterize the Receiving Water.* The antidegradation guidance establishes differing restrictions on the lowering of water quality and requirements for an antidegradation review depending on both the quality of the receiving water and the character of its use designation. ONRWs are identified at this point in the process; all other waters are characterized pollutant by pollutant as either achieving or not achieving the applicable fishable/swimmable water quality criteria defined elsewhere in the proposed Guidance. Where the water quality is achieving the water quality criteria for a pollutant, that water is considered a HQW with respect to that pollutant. Other special designations applicable to Lake Superior are discussed separately in the proposed Guidance. Two outcomes are possible, and resulting implications are as follows:

i. Waters whose quality does not achieve the applicable water quality criteria for any parameter cannot be lowered in water quality with respect to that parameter. ONRWs cannot be lowered in water quality except for lowering of water quality related to short-term, temporary (i.e., weeks or months) activities. That is, there can be no long-term change in ambient water quality in ONRWs except for improvement; or

ii. Actions that may significantly lower water quality with regard to a pollutant for which that water is a HQW can only be allowed if an antidegradation demonstration is provided and the regulatory agency determines that it adequately supports the lowering.

C. Activities Covered by the Great Lakes Antidegradation Guidance

The antidegradation guidance applies to any activity over which independent regulatory authority requiring compliance with water quality standards exists, that may result in a lowering of water quality in any water body in the Great Lakes System. The activities addressed include those resulting in point source discharges of pollutants to a water body and those that result in nonpoint loadings of pollutants to a water body. As discussed in detail in B.3.a above and C.3 below, EPA expressly intends for this proposed Guidance to be applied to nonpoint source activities, to the extent that regulatory authorities exist, but this proposed Guidance does not create any new regulatory authorities.

The proposed Guidance establishes an antidegradation policy that differs in certain respects from the existing Federal policy to account for the characteristics of the Great Lakes System, while retaining the basic framework of the Federal regulation. As is the case with the Federal regulation, the Great Lakes Antidegradation Standard establishes differing levels of protection against degradation based on the water quality in the affected water body.

1. Distinction Between High Quality Waters, Outstanding National Resource Waters, and Other Classes of Waters

a. *Existing Federal Policy.* EPA has defined a "tiered" antidegradation approach for the protection and maintenance of water quality. The Federal antidegradation policy at 40 CFR 131.12 establishes three tiers of protection on the lowering of water quality in a water body and a fourth requirement applicable to thermal discharges.

The first tier, applicable to all waters, requires protection and maintenance of all existing uses of the water body and the level of water quality necessary for those uses. Under tier 1, water quality in any water body can be lowered only to the point at which all existing uses are still fully protected. It is not permissible to allow water quality to be lowered to the extent that an existing or designated use is impaired. Under existing Federal policy no justification is required in order to lower water quality to the level necessary to maintain the "existing use."

The second tier provides protection of actual water quality in water bodies that support the propagation of fish, shellfish, and wildlife and recreation in and on the water ("fishable/swimmable"). Limited degradation of such HQWs may be allowable if necessary for important social and economic development in the areas in which the waters are located, but only after public involvement and intergovernmental coordination, and only as long as the water quality remains adequate to be "fishable/swimmable" and fully protects existing uses.

The third tier affords special protection to waters that have been designated Outstanding National Resource Waters (ONRWs) by the States or Tribes. The water quality in ONRWs must be maintained and protected. Short-term temporary changes may be consistent with that level of protection.

b. *GLWQI Guidance.* The Great Lakes antidegradation standard in the proposed Guidance retains the tiered structure of the Federal policy, but is more specific in certain respects.

The first provision requires, in part, that the water quality necessary to protect existing uses be maintained and protected. As with the Federal policy, this provision is intended to ensure that under no circumstance is the water quality reduced to the extent that a criteria derived to protect an existing use is exceeded. The proposed Guidance explicitly refers to the definition of existing uses found in the Federal water quality standards regulations, in large part to distinguish the application in this provision of existing uses from designated uses. During Work Group deliberations on the proposed Guidance, concerns were raised by several parties that the Federal policy had been incorrectly interpreted

by many States around the country as applying only to designated uses, as they are defined by the water quality standards regulation. Further concern was expressed that designation of uses by States or Tribes would not thoroughly cover all existing uses of a water body. The intent of the language chosen for the proposed Guidance was to clarify the effect of the language in the Federal policy and ensure that deficiencies in the State or Tribal use designation procedures would not limit the protection to be afforded water quality under the Great Lakes antidegradation guidance. For the purposes of this proposed Guidance, for any water body in which the water quality attained on or after November 28, 1975, is equal to or better than that required to support a specific use, that use is considered an existing use, whether or not it has been so designated in a State's water quality standards. In no case can the water quality be lowered below that level required to protect and maintain such existing uses.

The first provision of the Great Lakes antidegradation standard differs from the existing Federal policy in that it explicitly prohibits the lowering of water quality in situations where either an existing or a designated use is impaired. The Federal policy does not include the designated use reference. This prohibition is applied on a pollutant by pollutant basis and serves as a restriction on the specific pollutant or pollutants that are impairing the designated use. EPA considers a water body to be impaired where the water quality criterion necessary to maintain the existing or designated use for a pollutant or pollutants is exceeded. While this proposed provision differs from the existing Federal antidegradation policy on its face, it is not more stringent than section 301(b)(1)(C) of the CWA or the other regulations that EPA has adopted to protect water quality. In particular, the existing water quality-based permitting regulation (40 CFR 122.44(d)(1)) for the NPDES requires the development of effluent limitations that achieve the water quality standards applicable to the receiving water. Similarly, the regulations (40 CFR 130.7) and guidance on the establishment of total maximum daily loads, wasteload allocations, and load allocations require that applicable water quality standards be attained and maintained. Thus, the prohibition in the proposed Guidance on the lowering of water quality in situations where a designated use is impaired simply brings the antidegradation guidance into explicit conformance with other regulatory requirements regarding the protection of water quality. In the context of the whole of the proposed Guidance, this provision would preclude the lowering of water quality for a pollutant or pollutants in situations where the concentration of the pollutant or pollutants exceeds the proposed Great Lakes water quality criteria.

EPA also believes that it would be consistent with the policies of the GLWQA to prohibit any lowering of water quality in those waters in the Great Lakes System which do not meet the goal uses listed in section 101(a) of the CWA for the pollutant or pollutants that impair those uses. The CPA requires that the proposed Guidance not only be consistent with the CWA, but also conform with the objectives of the GLWQA. The purpose of the GLWQA is to restore and maintain the chemical, physical, and biological integrity of the waters of the Great Lakes Basin Ecosystem. Among its objectives is the restoration of beneficial uses, regardless of whether they are designated uses. The term beneficial uses is not specifically defined in the GLWQA; however, impairment of beneficial uses is explicitly defined in Annex 2 to the GLWQA as adverse effects on a list of uses. Among the listed beneficial uses that might be impaired are uses that are analogous to the fishable/swimmable uses in the CWA. EPA believes that it is reasonable to conclude that the beneficial use provisions of the GLWQA encompass the relevant portions of the fishable/swimmable goals of the CWA.

EPA considered an explicit proposal prohibiting any lowering of water quality in those waters in the Great Lakes System which do not meet the goal uses listed in section 101(a) of the CWA for the pollutant or pollutants that impair those uses. Such a provision would have served the objectives of the GLWQA by working toward the restoration of beneficial uses. It was based on an ecosystem approach, taking into account the unique characteristics of the Great Lakes System, where the whole is only as healthy as its parts. While the allowance of increased discharges with only a localized effect might be acceptable in the context of a different aquatic system, an argument can be made that in order to account for the unique characteristics of the Great Lakes System (see Great Lakes States' Experience, A.1.c. above), any increased addition of a pollutant or pollutants to a waterbody in the Great Lakes System which has not attained the beneficial uses for that pollutant or pollutant should be prohibited. Where the water quality standards for fishable/swimmable uses are not achieved, the beneficial uses are likewise impaired.

This provision is not proposed in the proposed Guidance because EPA believes that it would be redundant with the provisions protecting existing and designated uses discussed above. That is, the existing uses are, or the designated uses will be, fishable/swimmable. EPA may reconsider this position if other parts of the proposed Guidance change such that the above redundancy no longer exists.

The second tier of the Great Lakes antidegradation standard is identical to the existing Federal policy in most respects. Both require the protection and maintenance of water quality that exceeds (i.e., is better than) the level necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the water, except in limited circumstances. In both, such circumstances are limited to those in which the State finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. Finally, both require that in allowing such degradation, the State assure that water quality adequate to protect existing uses is fully maintained, and that there is achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost effective and reasonable best management practices for nonpoint source controls. The information that is developed and utilized to make a decision about the lowering of water quality in a high quality water is termed an antidegradation demonstration.

The Great Lakes antidegradation standard is more specific than Federal policy in one respect, however. Whereas the existing Federal policy is silent regarding the manner in which water quality is assessed to determine if it exceeds the level necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the water, the Great Lakes standard explicitly requires that water quality be assessed on a pollutant-by-pollutant basis. Under the Great Lakes antidegradation standard, where, for any parameter, the water quality exceeds that level necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter and that quality shall be maintained and protected, except when, as described

above, an antidegradation demonstration adequately justifies the lowering of water quality.

This approach is consistent with National guidance, which indicates that "all parameters do not need to be better quality than the State's ambient criteria for the water to be deemed a high quality water" and that EPA believes that "it is best to apply antidegradation on a pollutant-by-pollutant basis." ("Application of Antidegradation Policy to the Niagara River", memorandum from Martha G. Prothro, Director, Office of Water Regulations and Standards to Richard L. Caspe, Director, Water Management Division, Region II, dated August 4, 1989, which is available in the administrative record for this rulemaking). The rationale provided for this recommendation is that other approaches would result in "a potential for a large number of waters not to receive antidegradation protection which is important to attaining the goals of the Clean Water Act to restore and maintain the integrity of the Nation's waters."

The pollutant-by-pollutant focus on water quality also represents a reasonable, workable approach to antidegradation in the context of the water quality criteria for the Great Lakes System that are being proposed in the proposed Guidance. These criteria are intended to support the existing fishable/swimmable use of the Great Lakes System waters and create a de facto designated fishable/swimmable use for the Great Lakes System. Where such criteria are achieved, the water is, for those pollutants, of a quality sufficient to support fishing and swimming, and is high quality. There is no opportunity to lower water quality for the pollutants in waters where the criteria for those pollutants are not achieved.

EPA requests comment on an alternative approach to assessing water quality that would look at water quality as an "all or nothing" proposition, based on whether or not all applicable numeric water quality criteria are met. Under such an approach, failure of any pollutant to achieve the water quality criterion would indicate that the water body was not supporting the use that the criterion was designed to protect and, therefore, could not be degraded with respect to any pollutant. The criteria proposed establish a de facto fishable/swimmable designated use for the entire system. The "all or nothing" approach would say that if any pollutant exceeds one of the Great Lakes criteria, the water body would not be supporting the designated use. Because there are substances in the Great Lakes System that presently exceed the Great Lakes criteria, the "all or nothing" approach would, from the outset, preclude any lowering of water quality for any pollutant, and would continue to do so until such time as all criteria are met. EPA believes that the proposed Guidance is more reasonable than this alternative because, in combination with the implementation procedures proposed in appendix F to part 132, it would require that loadings of pollutants not supporting the designated use be restricted (i.e., the antidegradation procedures would prohibit any additional lowering of water quality for such pollutants), but would recognize that for other pollutants unused assimilative capacity exists such that the loadings for such substances could be increased and criteria for those pollutants still achieved. EPA further believes that the proposed approach is more appropriate in light of the national water quality-based permitting approach (40 CFR 122.44(d)(1)), which requires controls on pollutants the discharge of which has the reasonable potential to cause or contribute to an exceedance of State water quality criteria, but does not require controls on, or prohibit increases in the discharge of, other pollutants.

EPA requests comment on a second alternative approach that would also look at whether all criteria were being met in a water body in order to determine the level of protection provided by antidegradation. In this approach, if any pollutant was exceeding an applicable criterion, water quality could still be lowered with respect to other pollutants after an antidegradation demonstration review. The antidegradation demonstration would, however, be less rigorous than if all the pollutants in the water body were achieving applicable criteria.

As with the all or nothing approach described above, under this approach one would determine that a water body was not high quality if any pollutant exceeded an applicable criterion. However, the lowering of water quality for all pollutants would not be prohibited when any pollutant exceeds a criterion. Instead, it would allow for lowering of water quality for those pollutants that were meeting criteria. This approach also differs from the proposed approach, which would similarly allow for lowering of water quality for such pollutants, in that it would require a less rigorous antidegradation demonstration in such cases. This alternative might be viewed as a middle ground between the all or nothing approach and the proposed approach, or a tier 1½ level of protection, in situations where waters are not meeting criteria for some pollutants, but are meeting criteria for others. EPA welcomes comment on this approach, particularly with regard to the level of antidegradation demonstration that should be required to justify lowering of water quality in the situation it covers. EPA is also interested in whether commenters believe that such an approach would be adequately protective of the Great Lakes System.

EPA requests comment on a third alternative that would rely on a generic measure of water quality as opposed to water quality criteria for individual pollutants. Under such an approach, a State would use a measure of water quality that integrates chemical water quality criteria, biological criteria, and other appropriate criteria to assess the quality of a water body and determine if it is a high quality water subject to the tier 2 level of protection. Such an approach could also potentially be used to assess whether water quality is significantly lowered as a result of an increased discharge to a water body. Such an approach is not proposed in the proposed Guidance because EPA is unaware of any such generic measures that adequately integrate all of the subtle effects on water quality that are captured by the independent application of numeric water quality criteria and other appropriate State derived water quality criteria. The reader is referred to EPA's June 19, 1991, "Policy on the Use of Biological Assessments and Criteria in the Water Quality Program" and EPA's March 1991 "Technical Support Document for Water Quality-based Toxics Control", which are both included in the administrative record for this rulemaking, for a more complete discussion of the subject of independent applicability. Nonetheless, EPA would be interested in any new information that might address the applicability of such an approach in the context of antidegradation, and encourages commenters to provide such information.

EPA also requests comment on a fourth alternative approach for defining water quality, not proposed in the proposed Guidance, that would allow the evaluation of mixtures, rather than individual pollutants. This approach would evaluate the net effect of a discharge on water quality and determine whether the discharge improved or lowered water quality on the whole.

Under a mixture approach, a discharger could demonstrate that the

effects of increasing the discharge of one or more individual pollutants in a discharge would be offset by a concurrent decrease in one or more other pollutants. Using a technique such as toxicity equivalency factors (TEFs), the discharger would have the opportunity to show that the net toxicity or adverse effect on water quality of the proposed discharge would not be greater than the current discharge. If successful in such a showing, the permitting agency could determine that water quality would not be significantly lowered and the change in the discharge of pollutants to the water body would not be subject to an antidegradation demonstration.

The mixture approach is of interest because it would allow for trading of pollutant loadings to most efficiently maintain water quality. The approach proposed in the proposed Guidance would require that the change in the loading of each pollutant be evaluated separately to determine if it is necessary for important social and economic development. In contrast, the mixture approach would not require an antidegradation demonstration when some pollutant loadings were proposed to increase provided that others were reduced and the net effect was determined to be no adverse change in water quality. Because it would allow a regulated entity to determine where it could most efficiently reduce or prevent pollutant loadings, with the incentive of avoiding antidegradation demonstration requirements, the mixture approach has the potential to be less costly than other approaches while still maintaining or improving overall water quality.

Concerns with implementation of the mixture approach have led EPA to not propose it in the proposed Guidance. These are described below and EPA invites comment on each.

The mixture approach requires that the toxic effects of the chemicals in a discharge interact in a known way to produce a specific effect. The subject of additivity of toxic effects and the development and use of TEFs are discussed in more detail in section VIII.D. of the preamble. These concepts were considered for inclusion in the Great Lakes Guidance, but the proposed Guidance does not provide for their use. EPA has concerns regarding the practical application of these concepts, in particular as they would be applied in complex effluents. To determine the net toxic effect of a discharge requires that the pollutants in the discharge have comparable toxic endpoints, which is not necessarily the case for many pollutant mixtures in effluents. TEFs have been used to relate toxicities of homologues within families of pollutants, such as the chlorinated dibenzo-p-dioxins, or between toxicologically similar families, such as the chlorinated dibenzo-p-dioxins and the chlorinated dibenzofurans. TEFs may also be applicable to other classes of pollutants, such as metals, but their applicability would require that the pollutants have similar toxic effects and the same mode of action. Therefore, the use of TEFs would appear to have limited applicability for many pollutant mixtures in effluents. While the use of whole effluent toxicity as a measure of the effect of a mixture is appropriate in addressing effects on aquatic life, it does not address effects on human health or wildlife, and does not address all toxic endpoints. Use of whole effluent toxicity alone, therefore, would not form the basis for an acceptable mixture approach. EPA invites comments and suggestions as to how these technical issues could be addressed.

To accurately assess the overall effect of a discharge on water quality, the mixture approach could require that a number of pollutants in the discharge be factored into the analysis to determine the net change in water quality. This analysis could prove to be burdensome. In addition, in order to maintain the specific pollutant discharge reductions which offset the increases in other pollutants, the mixture approach could require the establishment of limitations on substances that would otherwise not have required limits. The Clean Water Act and Federal regulations currently define the minimum requirements with respect to pollutants that must be limited to protect water quality (40 CFR 122.44(d)(1)), and the guidance proposed in procedure 5 of appendix F to part 132 provides additional direction on this decision. EPA invites comments and suggestions on how interactions of pollutants could be assessed and considered within the context of the Antidegradation Policy to address mixtures of pollutants, and on how to establish guidelines on the pollutants to include in a mixture analysis. EPA is also interested in information on current practices that might be used to help set such guidelines.

2. Significant Lowering of Water Quality

For those waters in the Great Lakes in which the water quality exceeds the levels necessary to support the fishable/swimmable goal of section 101(a)(2) of the Clean Water Act, termed high quality or tier 2 waters, the Great Lakes Antidegradation Guidance procedures identify the criteria that must be satisfied before a decision can be made to allow water quality to be lowered significantly. EPA and the Great Lakes States have chosen to prioritize actions that pose a threat to the protection and maintenance of water quality in high quality waters by focussing the proposed Guidance on "significant lowering of water quality." The proposed Guidance requires that high quality waters (HQWs) not be significantly lowered in quality unless justified to the satisfaction of the regulatory agency through an antidegradation demonstration.

Significant lowering of water quality is defined in the proposed Guidance. The definition differs for bioaccumulative chemicals of concern (BCCs) and all other pollutants. The BCCs and the rationale for giving such chemicals a higher priority in the Great Lakes System are topics discussed in detail elsewhere in the proposed Guidance. In general, any increase in the rate of mass loading of any BCC is considered to result in a significant lowering of water quality. The only exception to this rule occurs when the increase in the observed mass loading rate of a BCC is not associated with a discernable action at the source (point or nonpoint) of the BCC, and is, therefore, likely to be an apparent rather than real increase.

The term "action" is to be interpreted very broadly and will include, for point sources, activities or combinations of activities that contribute pollutants (BCCs) to the waste stream, and thereby the water body, such as, but not limited to, creation of a new source, addition of a new process or product line at an existing source, expansion of processing capacity, modifications of the waste handling or treatment processes, changes in raw materials, and new sanitary or industrial hookups to a municipal sewer system. Generally, simply increasing the volume of the discharge with no addition of a BCC pollutant to the waste stream is not considered an action that would trigger an antidegradation demonstration. Similarly, for nonpoint sources, where independent regulatory authority requiring compliance with water quality standards exists an action might be a new construction activity or development that contributes new or increased pollutant loading from nonpoint sources or installation of a new factory or incinerator that might be a source of air pollutant fallout into the Great Lakes System.

The link in the definition between an increase in the rate of mass loading of a BCC and a discernable action is intended to prevent apparent increases in the rate of mass loading from triggering a full antidegradation

demonstration. EPA and the States were concerned that at times little data would be available to characterize baseline mass loading rates at the time decisions were being made regarding NPDES permit requirements or other such control requirements. Subsequent monitoring of the mass loading rates might reveal an increase above that indicated by the analysis of the initially available data, due solely to data variability and not to an actual increase in the rate of mass loading. To address this concern, the definition provides that an increase in the measured rate of mass loading of a BCC must be tied to an action at the source of the pollutant for it to be considered significant lowering of water quality that requires an antidegradation demonstration. This concern was also considered in the development of alternative control requirements that could be imposed on an entity to maintain water quality (e.g., existing effluent quality restrictions), which are discussed later in the proposed Guidance.

For pollutants other than BCCs, significant lowering of water quality is generally considered to occur whenever a source seeks a change in its permit limits (or a change above a de minimis increase in the rate of mass loading). For nonpoint sources, where independent regulatory authority requiring compliance with water quality standards, a significant lowering of water quality is generally considered to occur whenever the rate of mass loading authorized by the governing nonpoint source program is increased. Two exceptions to this general rule exist for non-BCC pollutants. The first exception occurs when the ambient concentration of the pollutant in the affected water body, outside of the designated mixing zone, where applicable, will not increase. The Director may also look at the effect of the increase on the sediments and biota to determine if they will be adversely affected. The second exception may result where the increase is de minimis, or insignificant, in comparison to the unused assimilative capacity of the receiving water for that pollutant. The de minimis demonstration is discussed in detail later in this notice.

EPA believes that the above definition of significant lowering of water quality for non-BCC pollutants is adequate to maintain and protect water quality in the Great Lakes System. It does not undercut the requirement that limitations protect existing uses, i.e., protect all applicable water quality standards. Rather, it limits the requirement to conduct an antidegradation review to situations when a source sought to increase existing permit limitations on the rate of mass loading, except as the increase is de minimis or there would be no change in ambient water quality, and thereby will limit the number of actions subject to a full antidegradation review. EPA believes that this is an appropriate balance between the need to protect water quality for these substances and the burden, to both the regulated community and the regulatory agencies, of conducting an antidegradation review. EPA welcomes comments on this position and specifically requests information on situations where this provision for non-BCCs may fail to adequately protect and maintain water quality.

Finally, the definition contains a provision that allows the Director to make case-by-case determinations regarding the significant lowering of water quality based on best professional judgement. This provision is intended to give the Director flexibility to designate actions that might have fallen outside of the other provisions of the definition, yet are considered by the Director to be important enough to warrant a full antidegradation review.

EPA emphasizes that the definition of significant lowering of water quality is intended to cover actions that lower water quality. It is not EPA's intent to cover, under antidegradation, increased discharges that do not contribute pollutants to the water body. Furthermore, for BCCs the increased rate of loading must be associated with an action by the regulated entity. As discussed above, EPA intends that the term "action" be associated with activities that contribute pollutants to the water.

For example, the antidegradation guidance is intended to cover the situation in which an industry that discharges BCCs to the Great Lakes System increases its rate of production, and with the production, the rate at which these pollutants are added into the water via its waste stream. In contrast, another situation may have an industry that draws cooling water from a water body in the Great Lakes System, and discharges that water back into the same water body without adding or removing any BCCs. If the industry wanted to increase the amount of cooling water it pumped through the facility, the increased rate of BCC loading in the effluent due solely to background pollutants from the water body would not trigger an antidegradation demonstration.

The determination of whether a discharge results in the significant lowering of water quality differs from decisions regarding whether a pollutant must be limited to protect water quality criteria and at what level the limitation is established. The latter decisions are addressed by the implementation procedures proposed in the proposed Guidance. The reader is referred to the preamble discussion of procedure 5, "Reasonable Potential to Exceed Numeric WQSs" (see section VIII.E of appendix F to part 132) for additional information.

EPA believes that the rule is sufficiently clear in these areas, but would welcome comment on whether the rule requires clarification. Commenters are encouraged to provide suggested changes to the rule that would accomplish the clarification.

EPA requests comment on the proposed approach to defining significant lowering of water quality and is particularly interested in comments on the requirement that an increase in the rate of mass loading of BCCs be tied to an action for it to be considered a significant lowering of water quality. In particular, does the definition place an undue burden on the regulatory agency to identify a specific causative action or actions, or, alternatively, on the regulated entity to prove that no action occurred? Also, where data exist, and are considered by the regulatory agency adequate to demonstrate a long-term gradual increase in the rate of mass loading of a pollutant, should such an increase be considered a significant lowering of water quality even when no specific causative action or actions can be identified? Such situations could result from aging waste treatment processes, which could be considered an "action" by the Director. EPA welcomes comment on whether the proposed Guidance should be clarified to more explicitly address this and other similar situations.

EPA also requests comment on whether the definition of significant lowering of water quality should distinguish between BCCs and other pollutants. In particular, EPA is interested in whether BCCs would be adequately controlled if the same definition of significant lowering of water quality as is applied to other pollutants were to be used for BCCs. Such an approach would have the effect of tying the definition of significant lowering of water quality for all pollutants to increases in permit limits. It would provide opportunity for a de minimis demonstration for increases in limitations on BCCs. It would also provide opportunity for an entity to attempt to demonstrate that the ambient concentration of the BCC would not increase. Other possible approaches

might restrict application of the de minimis test or the demonstration of no ambient change, or both, to non-BCCs, while still tying the definition of significant lowering of water quality for any pollutant to permit limit increases. EPA invites comment on these approaches and suggestions for others that should be considered. EPA also welcomes suggestions regarding any changes or specific requirements that should be made or added to the de minimis test and the demonstration of no ambient change to address BCCs if the definition of significant lowering of water quality were to be changed as discussed above.

3. Covers All Pollutant Sources (Point and Nonpoint)

As has already been discussed briefly, the antidegradation guidance covers any regulated activity, the result of which might be the lowering of water quality in the Great Lakes System. Such regulated activities are not limited to programs administered under the Clean Water Act, such as the NPDES and section 404 permitting programs. While this proposed Guidance does not create any new regulatory authorities that can be used by Federal, State, Tribal, or local regulatory authorities in expanding control of pollutant sources, it provides them with a framework for making consistent decisions regarding the protection and maintenance of water quality within existing regulatory authorities, where such authorities require compliance with water quality standards. One set of mechanisms that EPA believes will facilitate the application of the proposed Guidance to all sources of pollutants to the Great Lakes System is the Lakewide Management Plan (LaMP) that will be developed for each Lake. LaMPs are required by Annex 2 of the GLWQA to facilitate the restoration and protection of beneficial uses in the open waters of the Lakes. In addition, the CPA establishes a schedule for the completion of the Lake Michigan LaMP. The LaMPs will provide an integrated management tool to address all pollutant sources and coordinate all applicable regulatory authorities. While EPA feels that LaMPs will facilitate the application of this proposed Guidance, completed LaMPs are not prerequisites for its effective application, and regulatory authorities cannot delay the use of this proposed Guidance pending the development of a LaMP. EPA welcomes comment on alternative approaches to clarify within the proposed Guidance that it is applicable to both point and nonpoint sources of pollutants to the Great Lakes System, and to ensure that it is utilized in regulatory decision-making whenever appropriate.

4. Exemptions

The antidegradation guidance defines several actions or situations that will generally not be considered subject to the restrictions imposed by the antidegradation procedures. These exemptions are intended to cover actions that might lower water quality for a short duration, where the lowering is reversible, especially where the action will improve water quality over the long term. They also address emergency situations, which require immediate response to protect public health or welfare. The Director has the ability on a case-by-case basis to require that an otherwise exempted action comply with the antidegradation procedures.

There is a broad exemption provided for actions the effect of which is limited to a short-term, temporary lowering of water quality. The Federal antidegradation policy allows short-term, temporary changes in water quality in ONRWs, with no requirement for an accompanying antidegradation demonstration, a provision that was carried over into the Great Lakes antidegradation guidance. EPA believes that it is reasonable, since short-term, temporary lowering of water quality is allowable in the category of waters given the very highest degree of protection, the ONRWs, that similar allowance should be made for high quality waters.

The proposed Guidance places bounds on the timeframe that will be considered acceptable for an event to be considered a short-term, temporary lowering of water quality. For the effect of an action to be considered a short-term, temporary lowering of water quality, the effect must be limited to weeks or months in duration. This definition is the same as has been considered by EPA when drafting other guidance on water quality standards. It provides considerable flexibility to the Director to account for the specific characteristics of the pollutant involved, the receiving water, rate of mass loading, and so on, when deciding on whether the lowering may be short-term and temporary. While not explicitly excluded by the timeframe specified, actions that lower water quality for a year or more should only rarely be considered short-term and temporary.

Exemptions are also provided for certain emergency situations, which may result in a lowering of water quality. The first such exemption involves non-prohibited bypasses of wastewater treatment systems. Bypasses are defined and generally prohibited in the Federal NPDES regulations at 40 CFR 122.41(m). The regulations make exception to the general prohibition for instances in which a bypass is unavoidable to prevent loss of life, personal injury, or severe property damage, and there is no feasible alternative to the bypass. Similarly, the guidance provides an exception for Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) response actions and those taken under similar Federal or State authorities. CERCLA response actions are taken to alleviate emergencies resulting from releases into the environment of hazardous substances, and pollutants or contaminants which may present an imminent and substantial danger to public health or welfare. EPA believes that it would generally be infeasible and inappropriate to hold these emergency situations to the restrictions and procedural requirements of the antidegradation guidance.

The exemption from the antidegradation procedures does not exempt such actions from other requirements with which they are expected to comply. For instance, CERCLA response actions are required to comply with all applicable, or relevant and appropriate requirements, a term that is defined in the Federal regulations and includes all State water quality standards applicable to the water body. Similarly, the NPDES regulations prohibit bypasses in all but a very limited number of situations. The exemption to the antidegradation procedures does not alter the bypass prohibition in the NPDES regulations, but only provides relief from the antidegradation requirements for those bypasses not otherwise prohibited.

EPA welcomes comments on the exemptions identified in the proposed Guidance. In particular, EPA is interested in comments on the exemption for short-term, temporary lowering of water quality regarding both the appropriateness of such an exemption and the timeframes identified.

EPA also considered a broader exemption for remedial actions taken pursuant to CERCLA, or other similar Federal or State authorities. Remedial actions differ from the response actions discussed above in that they are generally long term, non emergency clean up activities associated with historical contamination. Remedial actions may improve water quality over the long term but result in a temporary lowering of water quality in the same surface water body over an extended

period (i.e., longer than would satisfy the requirements for an exemption for short-term, temporary lowering of water quality). In many instances the contamination remediated by such actions will be adversely affecting a surface water body, whether through contaminated runoff, contaminated groundwater percolating into the surface water, in-place sediment contamination, or other similar mechanism. Remedial measures are generally designed to control or eliminate the source of the pollutants and clean up the contamination. However, the immediate result of a remedial action, in particular while it is being conducted, may be a lowering of water quality, for instance through the discharge or release of the contaminants from a ground water treatment system into a surface water, often the same water body that is already adversely affected by the contamination. This temporary lowering often extends beyond weeks or months, but may result in long term improvement in surface water quality. Even where the same water body is temporarily degraded, such discharges must ensure protection of water quality standards as they occur, and the net effect over the longer term may be beneficial to water quality. Other special provisions discussed later in the proposed Guidance regarding the antidegradation demonstration and decision might affect the need for any exemption for remedial actions. EPA requests comment on whether those special provisions are adequate or whether the exemptions should be expanded to cover CERCLA remedial actions.

5. Discharges of Fill Material in Wetlands

Section 404 of the CWA regulates the discharge of dredged or fill material into waters of the United States, including wetlands. Fill material means discharged material which converts waters of the United States to dry land or which changes the bottom elevation of waters of the United States. Permits for such discharges must be based on the section 404(b)(1) guidelines, 40 CFR part 230, which require, among other things, that discharges not violate applicable water quality standards and not cause significant degradation to the environment.

Both the Federal and proposed Great Lakes antidegradation policies require that existing uses be protected. Discharges of fill material in wetlands can be seen as automatically eliminating the use within the filled area. Thus, a literal interpretation of either antidegradation policy could flatly prohibit the issuance of any section 404 permit for a wetland fill. Since it is logical to assume that Congress contemplated that at least some such permits be issued under the framework of the CWA, EPA has interpreted the existing use provision in the Federal policy to be satisfied with regard to fills in wetlands if the discharge does not result in "significant degradation" of the aquatic ecosystem as defined under 40 CFR 230.10(c) of the section 404(b)(1) guidelines. For high quality waters, the same "no significant degradation" level serves as the floor below which no significant lowering of water quality can be allowed. EPA requests comment on whether the Great Lakes antidegradation policy should be interpreted in a similar way.

D. Existing Effluent Quality

1. Background

Controlling contamination of the Great Lakes System by BCCs is a very high priority of the Great Lakes States and EPA. EPA is proposing that any increase, above a defined baseline, in the rate of mass loading of a BCC from either a point or a nonpoint source be considered significant lowering of water quality. The antidegradation procedures established by this proposed Guidance require special controls on potential sources of BCCs to protect against any unreviewed significant lowering of water quality that would result from such an increase in the rate of mass loading of a BCC. In particular, they require that the future rate of mass loading of BCCs be restricted to levels that are representative of typical operation at the time that the Director is considering issuance, reissuance or modification of the applicable control document, unless an increase is justified through an antidegradation demonstration.

2. Options for EEQ Controls

The proposed Guidance is not specific on the control document requirements that the Director uses to restrict the rate of loading of BCCs, and provides the Director considerable latitude to establish conditions that fit the situation. The following discussion describes the alternatives that the regulatory agency can employ to implement the requirements of section II.D.1 of appendix E of the proposed Guidance, regarding the control of the loading of BCCs, which will be termed the existing effluent quality (EEQ) provision.

To consistently implement the EEQ provision of the proposed Guidance, each State or Tribe should develop procedures that will be followed when making control document decisions in all applicable programs. The procedures should specify the types of conditions that will be used to establish a baseline discharge mass loading rate for each BCC as control documents are reissued or BCC-related conditions are modified. In particular, the procedures should serve as a crosswalk between the Great Lakes Antidegradation Guidance and the various regulatory programs, by identifying which decisions within each program are affected by the proposed Guidance, the control documents utilized and the types of conditions that can be included within them. The control document requirements specified in such State or Tribal procedures must be enforceable to accomplish this objective. An increase in the rate of mass loading may be requested by the regulated entity in the future and may be allowed if the increase is consistent with the antidegradation demonstration and decision requirements of the proposed Guidance.

To determine EEQ, a pollutant-by-pollutant evaluation of the release or discharge ("effluent quality") must be conducted during preparation of a draft control document for reissuance. All data collected over the previous control document term (e.g., past five years) that are representative of typical operation should be utilized. Discharge monitoring reports, application information, compliance sampling inspection results, and information requests may all provide useful information for this analysis. Data that reflect upsets or bypasses (such as those situations defined in 40 CFR 122.41 for the NPDES program) should not be utilized.

In developing this recommendation EPA intends to define a data set that would allow a permit writer to establish what the typical loading rate from a discharger is (i.e., how is the discharger affecting water quality?), while trying at the same time to ensure the database is large enough for meaningful analysis. This recommendation parallels the NPDES regulations and guidance regarding development of production-based limits (see 40 CFR 122.45(b)(2)(i); 49 FR 38031, September 26, 1984; and Training Manual for NPDES Permit Writers, U.S. EPA, Office of Water, January 1993, pp. 4–4 through 4–6). By specifying the term of the preceding control document we are trying to ensure there are enough data points to make the evaluation meaningful, without making the period over which data were collected so long that the data would not be representative of normal

or typical operations. Where conditions affecting the discharge are not constant over the term, the regulatory authority has the flexibility to adjust the time period over which data are considered representative of the effluent quality at the time of reissuance. For example, an expansion that occurred in the last 1½ years of a permit term would likely result in only the last 1½ years' of data being evaluated as representative of the discharge at the time of reissuance. On the other hand, if operations were curtailed in the most recent months as a result of a business slow-down, the discharge data during the earlier years of the term may be more representative of typical operations.

The distribution of multiple data points should be characterized using appropriate statistical techniques. Appendix E of EPA's March 1991 "Technical Support Document for Water Quality-based Toxics Control" (TSD) provides a good background discussion of statistical applications to describe effluent quality, and to develop effluent limitations that are appropriate for the discharge. (This document is available in the administrative record for this rulemaking. Copies are also available upon written request to the person listed in section XIII of this preamble.) The TSD provides, in appendix E, a discussion of the derivation of effluent limitations based on actual discharge data (i.e., derivation of EEQ). It also provides procedures (see Tables 2, 3 and 4) which may, depending on the data set, be used to derive these numbers. As explained in appendix E of the TSD, it will generally be appropriate to use procedures which assume that the daily effluent data are approximately log-normally distributed. This assumption is consistent with the general experience of the EPA in evaluating effluent discharge data (see section 5.2.2 of the TSD), but may be overridden by the permit writer if the effluent data deviate seriously from this distribution. Where this is the case, alternative methods, such as non-parametric statistical techniques, may be useful to determine EEQ. Similarly, the procedures in appendix E of the TSD assume that the data are independent (i.e., not correlated with one another). Should this assumption not hold, alternative statistical techniques or other corrections may be appropriate. Appendix E of the TSD provides some suggestions on how this may be accomplished.

Analytic results that are below the quantification level should be factored into the development of EEQ as non-zero results using the procedures set forth in procedure 3B of the proposed implementation procedures (appendix F to part 132) or other appropriate statistical procedures (e.g., delta lognormal procedures from appendix E of the TSD).

Various options for incorporation of EEQ as a control requirement in a control document were considered during development of the proposed Guidance. The EEQ control requirements, in conjunction with any more stringent limitations otherwise required by the applicable regulations, such as technology-based and water quality-based effluent limitations in the NPDES program, must provide complete coverage of all BCCs. In addition, the proposed Guidance requires that control documents contain a condition prohibiting the discharger from undertaking any deliberate action which would result in the increase in the mass loading rate of a BCC above EEQ, without having first successfully completed an antidegradation demonstration and received State authorization for the increase. The following discussion covers the two principal options, which may be used either independently or complementarily, and a supplement which may be used in combination with either or both options. EPA invites comments on these options and welcomes suggestions regarding other alternatives that should be considered for EEQ controls.

a. *Option 1: EEQ as Numeric Mass Loading Rate Limitations.* In this option, a State will develop numeric effluent limitations that will serve to restrict the loadings of BCCs to their existing levels. In an NPDES permit, limits will generally be expressed as daily maxima or weekly averages and monthly averages. Other control document situations may call for alternative averaging periods.

Generally, calculations to determine daily maximum and weekly or monthly average numeric limitations to ensure that effluent mass loadings of a BCC do not increase above EEQ should follow this approach: Using appropriate statistical techniques, determine the daily maximum EEQ as the upper 99th percentile of the distribution of the daily data, and the weekly or monthly average EEQ as the upper 95th percentile of the distribution of the average of the daily data.

The resulting numbers, if more restrictive than otherwise applicable technology-based or water quality-based effluent limits, should be incorporated into the control document as daily maximum or weekly average, and monthly average mass loading rate limitations. Any exceedance of such limits would be a violation of the permit and subject to enforcement. Entities subject to such limitations that anticipate that production or process changes may result in exceedance of the EEQ limits will need to request an increase in the EEQ limits and justify such an increase through an antidegradation demonstration. When such a request is made prior to control document issuance, appropriate alternate effluent limitations that are based on the demonstration would be incorporated into the issued control document. Where such information becomes available during the term of the control document, the entity may request modification of the control document, subject to any applicable regulatory constraints on such modification, and submit supporting information including an antidegradation demonstration.

b. *Option 2: Narrative Prohibition Coupled with EEQ Notification Requirement.* Under this option, the draft control document would contain two separate conditions that, together, would serve to monitor the level of discharge of BCCs and restrict the permittee from undertaking actions, such as plant expansions, that would result in an increase in the mass loading rate of any BCC.

The first of the two conditions would be the narrative condition (limitation) described earlier. NPDES permit language that would accomplish this might read as follows:

"The permittee is prohibited from undertaking any deliberate action, where such action by the permittee would result in the increase in the mass loading rate of a Bioaccumulative Chemical of Concern [defined and listed elsewhere in the permit] above that established with the issuance of this permit. Should the permittee propose to take such action, the permittee must seek modification of this permit, and provide information including an approvable antidegradation demonstration to support the request."

The second of the two conditions would be a monitoring requirement with notification triggers. This condition would list all of the BCCs to which it applies, the required monitoring frequency, and the EEQ level (determined using the procedure for the daily maximum limitation under Option 1, i.e., the upper 99th percentile of the distribution of the daily data) for each listed pollutant. The second condition would also contain requirements that the permittee notify the Director of any exceedance of an EEQ level (notification trigger) and that

such notification specify the suspected cause of the exceedance.

If ongoing monitoring indicates that a substance has been discharged in excess of EEQ, it is the permittee's responsibility to notify the Director of the exceedance and the suspected cause. Failure to provide notification as required is a violation of the permit and subject to appropriate enforcement response. Receipt of such notification by the Director may prompt a review to determine if there has been a change at the permitted facility in violation of the narrative condition. It may also prompt reassessment of the EEQ level to determine if there is a need to modify the EEQ notification trigger to better reflect the actual rate of discharge.

Should the review of any information available to the Director, including that submitted pursuant to the EEQ notification condition, demonstrate that the entity has taken an action prohibited under the narrative, the entity would be in violation of the narrative condition. Such a violation would be handled in the same way as a violation of a numeric limitation.

c. *Supplement to Options 1 or 2: Establishment of Discharge Prohibitions to Maintain EEQ.* In addition to the requirements of Options 1 or 2, States may wish to specify in the control document that the discharge of listed BCCs not specifically limited or otherwise restricted in the control document is prohibited, or, alternatively, that such discharge is not authorized by the control document. This may be a particularly attractive alternative to a long list of pollutant limitations for BCCs that are known or believed to be absent in the discharge.

To adequately implement the requirements of section II.D of appendix E of the proposed Guidance, requirements under this supplemental action would have to be enforceable and tracked. The control document would include language that clearly establishes the prohibition or non-authorization and the list of pollutants to which it applies. It would require periodic monitoring to be used to assess compliance. Under this supplemental action, the control document would indicate that the discharge of a specific list of pollutants is not authorized, and specify the effect of detecting an unauthorized pollutant in the effluent. The effect may range from a violation of a limitation as in Option 1 to the triggering requirement as in Option 2, but it would be clearly specified in the control document.

3. Issues

During the Great Lakes Water Quality Initiative Technical Work Group discussions regarding the use of EEQ controls on BCCs to protect and maintain water quality in high quality waters, numerous issues were deliberated. In addition to comments on the general approach to using EEQ described above, EPA solicits comments on the issues and decisions discussed below.

a. *Punishment of Good Performers.* One criticism frequently made of the use of EEQ limitations and control requirements is that they are a disincentive to good performance by a regulated entity. In the context of an NPDES-permitted discharger, the rationale for this criticism is as follows. A "good performer" will seek to operate its treatment processes as efficiently as possible, or even design excess treatment capacity, in order to ensure that the technology-based and water quality-based effluent limitations in its permit are never exceeded. As a result of this good performance, the effluent quality of such a discharger is likely to be considerably below the limitations in its permit. The EEQ evaluation would result in the discharger receiving tighter EEQ-based limitations or control requirements, solely because of the discharger's good past performance. Furthermore, to the extent that the EEQ conditions are more stringent numeric limitations on the mass loading rate of the BCCs, that discharger would be put at higher risk of violating the limitations, even if it continued to operate as efficiently as it had in the past. Making the situation even more disagreeable to those raising this issue is the perception that "bad performers" are rewarded by the process, because their technology-based or water quality-based limits would likely not be tightened as a result of the EEQ analysis.

EPA and the Great Lakes States share the concern that the EEQ provision not be a disincentive to good performance, and the proposed Guidance is written to allow regulatory authorities the flexibility to utilize alternatives, such as identified above, that should help to alleviate the concern. In particular, Option 2 provides for permit conditions that require notification of an exceedance of an EEQ level, and such an exceedance only results in a permit violation when it is either not reported or is the result of an action by the permittee, which has not been approved by the regulatory agency under the Great Lakes antidegradation decision-making procedures. This approach still captures the EEQ concept, but it addresses in part the perceived disincentive associated with EEQ limitations. In particular, the concern that an EEQ limit puts a permittee at a higher statistically defined risk of a permit violation is avoided by this approach.

In addition, EPA believes that these concerns downplay the real risks of being what would be considered a "bad performer." While such a discharger might not see tightened restrictions or limitations on BCCs, it will still see EEQ restrictions or limitations, in addition to the applicable technology-based and water quality-based limitations. Minimally adequate or poorly operated and maintained treatment capacity or other such characteristics that would tend to characterize a "bad performer" will very likely result in a significant probability of violation of these limits. As EPA or the States consider the appropriate enforcement response to effluent limitation violations, they will take into account the factors that separate the "good performers" from the "bad performers." EPA believes that the increased likelihood of effluent limit violations and enforcement actions that result from being a "bad performer" will continue to be a strong incentive for good performance, even after EEQ restrictions are implemented.

EPA and the Great Lakes Steering Committee believe that it is appropriate to restrict the rate of mass loading of BCCs to EEQ to protect and maintain water quality in the Great Lakes System. EPA is not, through the use of EEQ to define effluent requirements or limitations, trying to force dischargers to install and operate additional waste treatment capacity, but only to operate and maintain their existing capacity so that the rate of mass loading of BCCs does not increase. EPA welcomes comments on other alternative approaches that should be considered that accomplish this objective, but might place less of a burden on the regulated community, in particular the "good performers." Also, as discussed above, under C.2. "Significant Lowering of Water Quality", EPA is inviting comment on whether the definition of significant lowering of water quality should be changed to focus on permit limit increases for all pollutants and thereby eliminate the focus on EEQ for BCCs. EPA is interested in whether commenters believe that such a change would remedy the perceived disincentive for good performance.

b. *Statistical Procedures.* The analysis of effluent data to develop EEQ estimates requires the use of statistical procedures. During development of the proposed Guidance, concerns were raised by many parties regarding the

procedures that should be applied and the implications. In particular, it was noted that no single formula could appropriately be used on all data sets and that all procedures would define some upper bound EEQ estimate, which would almost guarantee occasional exceedances of the estimate and the potential for violations of the corresponding effluent limitation.

EPA agrees that no single statistical formula will be appropriate for all situations. Thus, the proposed Guidance does not prescribe any specific formula or procedure to determine EEQ. Rather, the decision is left to be made by the regulatory authority on a case-by-case basis. Nonetheless, as described above and discussed more thoroughly in the EPA TSD, for effluent discharge data, it will often be appropriate to apply simple lognormal statistics to determine EEQ. In addition, the NPDES permit regulations specify the averaging periods that should generally define the permit effluent limits. Standard practice has been to apply the upper 99th percentile of the distribution of the daily effluent data as a maximum limit, and the upper 95th percentile of the distribution of the average of the daily effluent data as an average limit.

EPA notes that the proposed Guidance does not require that EEQ be expressed as numeric effluent limitations. However, EPA continues to strongly support the use of the probability expressed above in the characterization of EEQ. EPA has historically used these or similar probability levels in the context of effluent limitations guidelines development. Probability levels have also been used by EPA and the States in the development of individual permit effluent limits. It is not possible to derive numeric EEQ limits that guarantee 100 percent compliance; with any EEQ limit will come the statistical probability that the limit will be exceeded. The goal in establishing probability levels is to allow the regulatory agency to distinguish between adequately operated wastewater treatment plants with normal variability from poorly operated treatment plants. EPA invites comments and suggestions on other approaches that might be useful in place of or in addition to the statistical procedures discussed in establishing EEQ.

c. *Data Availability and Representativeness.* Many of the BCCs will have very little discharge monitoring data available from which to derive EEQ for any given source. This arises for a variety of reasons, ranging from simple lack of historical monitoring requirements because the discharger was not considered a potential source of the BCC, to lack of monitoring techniques sensitive enough to measure environmentally significant discharges. The focus of the Great Lakes antidegradation guidance on the BCCs raises the question of whether the periodic monitoring of all dischargers for the presence of BCCs should be required. The frequency of such monitoring would be determined by the regulatory agency based on the potential of the discharge to be a source of the BCC. EPA invites comments on this question and suggestions on the appropriate monitoring requirements for BCCs. EPA has estimated the potential cost to industrial and municipal facilities to monitor for the presence of BCCs in their discharges. Assuming that all industrial and municipal facilities monitor twice per year for BCCs having Tier I criteria, the total annual monitoring cost for Tier I BCCs are an estimated $10 million.

Decisions on control document EEQ requirements may have to be made based on very limited data, or on data which the regulatory agency considers questionable. Considerable flexibility is available to the regulatory agency to deal with such issues. If the regulatory agency is concerned that a BCC is in a discharge, reasonable additional data may be requested of the regulated entity prior to development of the control document under the information gathering authorities common to most environmental statutes. The EEQ conditions in the control document may also be tailored to address the quantity and quality of the data initially available to determine EEQ, through the use of restrictions other than numeric effluent limitations. EPA believes that the flexibility available to the regulatory agency to implement the EEQ requirements allows for sufficient options to address the data availability problems which might arise, while still ensuring that water quality is maintained and protected.

d. *Application to Municipalities.* During the Technical Work Group deliberations on the use of EEQ requirements, the issue of applicability of EEQ conditions to discharges to publicly owned treatment works (POTWs) was repeatedly raised. In particular, there was concern expressed that such requirements would restrict growth that had been previously contemplated in the design and public funding decisions involving the POTW. It was argued that POTWs have historically been designed, approved, publicly funded, and constructed with a built in growth assumption. The regulations at 40 CFR 122.45(b)(1) recognize this and call for the use of the design flow to develop POTW effluent limitations. This growth factor and the incremental increases in pollutant loadings accompanying growth were part of the initial public decision to construct a POTW, the argument went; therefore, it is not necessary to revisit these issues in an antidegradation analysis.

EPA notes that much of this discussion occurred when the Technical Work Group was considering requiring EEQ limits for all pollutants, which is not a requirement of the proposed Guidance. It was generally agreed that any relaxation in existing effluent limits that were not based on EEQ should necessitate antidegradation analysis. Similarly, any proposed expansion of POTW facilities that may result in an increased loading of pollutants to the receiving water over its design life, or the operation of a POTW beyond its design capacity was anticipated to be subject to antidegradation analysis. It was also generally accepted by the Work Group that the discharge of BCCs from POTWs would require EEQ analysis upon permit reissuance. These requirements are reflected in the proposed Guidance.

Consequently, EPA believes that the proposed Guidance addresses many of the unique concerns of POTWs associated with anticipated growth, by only requiring EEQ conditions for BCCs and keying the significant lowering of water quality for all other pollutants to increases in permit limits. EPA invites comment on whether the proposed Guidance adequately addresses the issue of anticipated growth by POTWs, and suggestions on how the proposed Guidance might be improved in this regard.

e. *Restrictions on Actions Versus Limitations on Pollutants.* Use of the type of conditions specified above in Option 2 also was the subject of considerable debate during the development of the proposed Guidance. Option 2 would require the use of a narrative prohibition on the implementation of any action by the regulated entity which would result in an increase in the rate of mass loading of a BCC above EEQ. This narrative prohibition, when coupled with monitoring and EEQ-based reporting trigger levels, would be expected to prevent the significant lowering of water quality, just as would numeric limitations on the BCCs. The primary debate centered on the use of a condition which prohibits an action rather than directly setting effluent limitations. A parallel concern involved

the use of narrative restrictions in lieu of numerical limits, in general.

EPA recognizes that, particularly in the NPDES permit program, it has traditionally focussed almost exclusively on the use of effluent limitations to control discharges and has, with limited restrictions, allowed the regulated entity considerable latitude in determining how to comply with the limitations. Generally, permits are not constructed to specify the treatment technologies and controls that must be used by a regulated entity. At first glance, the narrative prohibition on actions by a regulated entity that is included in Option 2 might seem to run contrary to this standard practice.

One reason for the traditional focus on numeric limitations is that, especially as involves water quality-based permitting, it is the quality of the effluent that is important, not necessarily the treatment or controls used to achieve that quality. In addition, one of the best measures of treatment plant performance is the quality of the effluent that the plant produces. In this sense, numeric effluent limits are often the most sensible type of permit requirement to use to ensure proper treatment system performance.

However, even within the context of the NPDES program, conditions are included in permits that specify actions that must be undertaken by the regulated entity in order to be in compliance with the permit. For instance, permits often include compliance schedules that specify actions to be accomplished by the permittee. The NPDES regulations also provide that permits may contain requirements for the implementation of best management practices. Finally, permits also currently contain prohibitions on certain actions, such as bypasses. Under the Clean Water Act, EPA is provided with broad authorities to establish permit conditions necessary to carry out the provisions of the Clean Water Act; such conditions are not limited to numeric effluent limitations. EPA believes that the Option 2 prohibition on actions which would result in an increase in the rate of mass loading of a BCC is consistent with current permitting practice and well within existing regulatory authorities. In addition, EPA is confident that well-constructed, clear narrative conditions can be tracked and enforced as effectively as numeric limitations.

f. *Statutory Authority for EEQ.* Questions were raised during development of the proposed Guidance regarding the statutory authority upon which EPA was relying in requiring EEQ to be used in the development of control document conditions.

Antidegradation policies are clearly authorized by the Clean Water Act (see sections 118, as amended by the CPA, and 303(d)). Under the Federal antidegradation policy, States and Tribes are provided with considerable latitude in defining the requirements necessary to protect and maintain water quality in HQWs. EPA is proposing, for reasons discussed in section C.2 of the preamble, that to protect and maintain high quality water in the Great Lakes System, it is necessary to restrict the significant lowering of water quality. Significant lowering of water quality in HQWs can only occur if an antidegradation demonstration adequately justifies the significant lowering of water quality and the Director approves such lowering. For the BCCs, in the Great Lakes context, EPA is proposing that any action that results in an increase in the rate of mass loading of a BCC to a HQW significantly lowers water quality. To prevent significant lowering of water quality from occurring as a result of such actions, the proposed Guidance requires that EEQ be maintained (e.g., that there be no increase in the rate of mass loading) until an antidegradation demonstration is performed and an increase approved by the regulatory authority.

In addition, as regards point sources, when the Great Lakes States and Tribes adopt antidegradation policies consistent with this proposed Guidance, as is required by the CPA, the policies will become the State and Tribal water quality standards or other requirements established pursuant to State law or regulation that are referenced in section 301(b)(1)(C). At that time, when the discharge of BCCs is from a point source subject to an NPDES permit, that permit must contain EEQ limitations or conditions, pursuant to section 301(b)(1)(C), to meet the requirements of the antidegradation policy.

g. *Ability to Accommodate a Return to Increased Production Levels Under Antidegradation.* The degree of flexibility that a regulatory authority has under the proposed antidegradation guidance to allow a return to a previous high production level (for example, through the resumption of a second shift) depends on when the previous high production level occurred. Consider the following scenarios:

Scenario 1: Permit issued with facility at production rate X; production is cut back after issuance to X minus 100; facility wants to return to X during permit term.

In this scenario, the return to the higher production rate would not be subject to an antidegradation review. On issuance the permitting agency would have established, for all pollutants, appropriate effluent limitations and, for BCC pollutants, loading rate baselines (i.e., EEQ) to reflect the production rate X. The effluent limits and EEQ baseline will not change during the term of the permit, even if production is reduced. When production returns to X, the effluent limits and EEQ baseline conditions would accommodate the increase, and the event would not be considered significant lowering of water quality.

Scenario 2: Permit issued with facility at production rate X; facility wants to increase production to X plus 100, a level attained previously.

In this scenario, the return to the higher production rate may be subject to antidegradation, depending on the timing of the previous production patterns and whether or not they are reflected in the effluent limits and EEQ baseline conditions established at the time of permit reissuance. As discussed above, information from the preceding permit term should be used to determine the effluent quality. The permit writer has the flexibility to use the most representative information from the preceding permit term in making the determination. The permit writer could account for an recent downturn in production by setting the effluent limits and establishing EEQ baseline conditions to reflect conditions prior to the downturn if information was available to suggest that the downturn was likely to be temporary. In contrast, if a production decrease was in evidence during the majority of the previous permit term and likely to continue,the permit would likely establish effluent limits and baseline EEQ conditions at the level representative of the downturn.

In summary, working within the underlying intent of the proposed antidegradation policy, there is some flexibility to account for temporary, generally recent, downward trends in production and effluent loadings under this scenario.

EPA requests comment on the operation of antidegradation as discussed above. In particular, EPA is interested in comments about whether the proposed Guidance provides sufficient flexibility to accommodate economic recovery in the Great Lakes region, while still preserving the intent of the antidegradation policy to protect and maintain water quality in the high

quality waters of the Great Lakes System.

h. *Relationship of EEQ to Implementation Procedure 8.* During development of the EEQ provisions in the proposed Guidance, concerns were expressed regarding EEQ limitations or restrictions that reflected nondetectable discharges. In particular, the relationship between the EEQ requirements of the Antidegradation Policy and the requirements of procedure 8 of appendix F to part 132 was questioned, and concerns raised that the EEQ requirements would necessitate fish bio-uptake studies (procedure 8.F.1 of appendix F). EPA believes that the EEQ and procedure 8 of appendix F provisions operate independently and that fish bio-uptake studies will not necessarily result from the application of EEQ requirements. Procedure 8 of appendix F requires that permits include certain provisions if the WQBEL for a pollutant is below the detection level. For BCCs, one of these provisions is a fish bio-uptake study to determine if the discharge of a pollutant is occurring at a rate or level that results in unacceptable accumulation in fish tissue. The requirements of procedure 8 of appendix F, including fish bio-uptake studies, only apply when the regulatory agency has determined, using procedures 3 and 5 of appendix F, that a WQBEL for the BCC in question is necessary.

Like the implementation procedures, the EEQ provisions of the Antidegradation Policy also direct that controls be placed on the discharge of BCCs. The regulatory agency may choose that the controls take the form of numeric effluent limitations, or may choose to use other mechanisms to maintain EEQ for the BCCs, such as were discussed under "Options for EEQ Controls". The basis for the EEQ restrictions, whatever their form, is to prevent the significant lowering of water quality. The EEQ restrictions are not based on implementation procedures 3 or 5 of appendix F. They do not generally take the place of WQBELs developed pursuant to these procedures. Consequently, they would generally not be subject to the fish bio-uptake study requirements of procedure 8 of appendix F. The regulatory agency is always free to require fish bio-uptake studies in conjunction with EEQ requirements, but such studies are not mandated by this proposed Guidance.

EPA is aware of only one circumstance in which EEQ permit conditions would necessarily require the use of fish bio-uptake studies, and this would result not from the antidegradation requirements, but because the regulatory agency would have chosen to use an EEQ limit in a permit in place of an otherwise necessary WQBEL. A regulatory agency may choose to include numeric EEQ effluent limitations for a BCC, which would otherwise be required to be limited by a WQBEL developed pursuant to procedures 3 and 5 of appendix F. If the EEQ limit was more restrictive than the WQBEL and would ensure compliance with the WQBEL, then the agency may choose to use it in the effluent limits table as a substitute for the WQBEL. Where such an application of EEQ required a limitation that was below the detection limit, the regulatory agency would have to apply procedure 8 of appendix F, including the fish bio-uptake studies.

EPA believes that the Antidegradation Policy and implementation procedures, as written, lead to the above conclusions. EPA would welcome comments and suggestions on how to clarify the proposed Guidance to remove ambiguity. EPA would also welcome comments on whether or not the proposed Guidance should be changed to require fish bio-uptake studies in conjunction with EEQ requirements for nondetectable BCCs.

E. De Minimis Lowering of Water Quality

1. Background

EPA and the Great Lakes States, in prioritizing situations that would be considered significant lowering of water quality in HQWs, drew a distinction between BCCs and other pollutants. As discussed in detail above, significant lowering of water quality for BCCs focuses on EEQ. In contrast, for pollutants other than BCCs ("non-BCCs") the definition of significant lowering of water quality keys off of increases in permit limits, and allows exemptions for de minimis increases and increases that result in no change in ambient concentration outside of any applicable mixing zone.

The "de minimis test" is a series of criteria that ensure that the lowering of water quality does not result from a BCC, and then assess the degree to which water quality is lowered by a pollutant, in comparison to the ability of the waterbody to assimilate the pollutant. Use of the de minimis test to exempt an action from an antidegradation review is a discretionary decision of the Director. Even when the lowering of water quality for a particular situation (i.e., a specific pollutant in a particular waterbody) may be considered de minimis and therefore not subject to antidegradation demonstration requirements, there may still be constraints on relaxing the limitation for the pollutant in question because of the requirements of the implementation procedures, such as those for margins of safety.

2. Detailed Description of De Minimis Test

a. *Specific Tests Included in De Minimis Demonstration.* For substances other than BCCs, a lowering of water quality may be considered de minimis if:

i. The lowering of water quality uses less than 10 percent of the unused assimilative capacity; and,

ii. For pollutants included on Table 5 of proposed section 132.4, at least 10 percent of the total assimilative capacity remains unused after the lowering of water quality.

The de minimis tests rely on the concept of assimilative capacity, which is the ability of a waterbody to receive the discharge of pollutants and still attain applicable water quality standards. The total assimilative capacity is determined as the product of the applicable water quality criteria times the critical low flow, or designated mixing volume in the case of lakes, for the waterbody in the area where the water quality is proposed to be lowered, expressed as a mass loading rate. The unused assimilative capacity is that amount of the total assimilative capacity not utilized by point source and nonpoint source discharges, including background. The unused assimilative capacity is established at the time the request to lower water quality is considered. The total assimilative capacity should remain relatively constant over time, changing only as the applicable criteria change or the critical low flow of the receiving water changes, for instance, due to physical diversions or new flow data used to calculate the critical low flow. The unused assimilative capacity will be redefined each time a de minimis test is conducted and may increase or decrease due to, for instance, improvements in water quality, or increased uses of the waterbody, respectively. EPA recognizes that some pollutants will not be amenable to this procedure for calculating total assimilative capacity (e.g., pH, color, alkalinity, dissolved oxygen, salinity, temperature). For such pollutants the Director should employ other techniques to determine total assimilative capacity, as appropriate.

With the first de minimis criterion identified above, EPA and the Great Lakes States and Tribes have established a threshold below which the lowering of

water quality may not be considered significant enough to warrant a thorough antidegradation review. It is proposed that a single action which lowers water quality less than ten percent of the total amount that might have been available to accommodate all new actions could be considered insignificant by the Director when determining if that action must satisfy antidegradation requirements. EPA and the Great Lakes States and Tribes believe that the 10 percent value chosen as the threshold represents a reasonable balance between the need of the regulatory agencies to limit the number of actions involving non-BCCs that are subjected to the detailed antidegradation demonstration requirements and the need to protect and maintain water quality. In particular, it is believed that any individual decision to lower water quality for non-BCCs that is limited to 10 percent of the unused assimilative capacity represents minimal risk to the receiving water and its ability to support all existing uses. The Director always has the ability to override the results of a de minimis test to determine that an action must satisfy antidegradation demonstration requirements if information is available to the Director that suggests that the lowering of water quality should be considered significant. Note also that each successive lowering of water quality on an individual waterbody segment will have to be smaller than the previous lowering, in absolute terms, for it to be considered de minimis. (For example, if the first time that water quality on a stream were lowered, the unused assimilative capacity was 100 pounds per day, the de minimis amount would have been up to 10 pounds per day. Presuming an action went forward as de minimis, using 9.5 pounds per day, the resulting unused assimilative capacity for that segment would be 90.5 pounds per day. The next action would have to involve an increase of less than 9.05 pounds per day to be considered de minimis, and so on.) EPA welcomes comment on this criterion and is especially interested in examples of de minimis thresholds that are currently used by States or Tribes in water quality decision-making, and the rationale that the State or tribe relied upon in the choice of the threshold.

The second criterion involves pollutants that would not be subject to the implementation procedures in this proposed Guidance. (These pollutants are listed in Table 5 of proposed section 132.4; the reader is referred to section II. F of this preamble for a discussion of these pollutants.) This criterion ensures that a margin of safety (MOS) is set aside for such pollutants so that the de minimis lowering of water quality cannot utilize the entire assimilative capacity. Under this criterion, an action involving non-GLWQI pollutants may be considered de minimis only if at least ten percent of the total assimilative capacity remains unused after the action occurs.

All pollutants that are covered by the implementation procedures are subject to the requirements related to TMDLs, WLAs, LAs and margins of safety (MOSs). In particular, the MOS requirements would set aside a portion of what the de minimis test terms the unused assimilative capacity when decisions are made regarding discharge limitations. Actions that result in a lowering of water quality, the size of which might be considered de minimis under the antidegradation procedures, might not be allowable under the implementation procedures, because the margin of safety requirements might preclude any increase of the discharge mass loading rate limits. In this manner, for the GLWQI pollutants, the Implementation and Antidegradation Procedures complement each other to ensure that de minimis decisions would not use up the entire unused assimilative capacity. However, as discussed below, under "3. Issues", EPA has concerns regarding the effectiveness of this procedure and is inviting comment on an additional alternative.

b. *Examples.* The following examples illustrate how the de minimis test works:

i. *Example 1.* In a stream tributary to a Great Lake, the most stringent applicable water quality standards for cadmium is 1.8 ug/L. The critical low flow of the stream is the 7Q10 of 3000 cfs. The resulting total assimilative capacity of this stream for cadmium is 29 pounds per day. At the time the request is made to increase the loading of cadmium to the stream, existing point and nonpoint sources and background contribute 14 pounds of cadmium per day to the stream segment, resulting in an unused assimilative capacity of 15 pounds per day. Provided that the increase sought is less than 1.5 pounds per day, the increase may be considered de minimis.

ii. *Example 2.* For a discharge directly to a Great Lake, the total assimilative capacity is based on an allowable dilution of 10 to one. Assuming that the background concentration of iron was 0 ug/L, to meet a chronic water quality standards for iron of 300 ug/L the effluent limit for iron would be 10 times 300 ug/L, which is 3,000 ug/L (or three mg/L). For a discharge of one MGD, the maximum allowable load is 25 pounds per day.

Analysis of available data shows that the background concentration of iron attributable to all point and nonpoint sources is 100 ug/L. Therefore, the unused assimilative capacity is 300—100 or 200 ug/L, which translates to 17 pounds per day. The de minimis amount for iron for the one MGD discharge is 10 percent of 17 pounds per day, or 1.7 pounds per day.

iii. *Example 3.* In a stream tributary to a Great Lake, the dissolved oxygen standard (a Table 5 "excluded" pollutant) is four mg/L at critical flow and temperature conditions. The existing daily average dissolved oxygen in the stream is six mg/L. The unused assimilative capacity is two mg/L. The de minimis dissolved oxygen impact is 10 percent of two mg/L or 0.2 mg/L. An assimilative capacity analysis of the tributary in question would be conducted to identify the biological oxygen demand (BOD_5) load that would achieve four mg/L, six mg/L, and the load increment that is equivalent to 0.2 mg/L of dissolved oxygen impact. A BOD_5 loading increase that corresponds to 0.2 mg/L dissolved oxygen impact could be considered de minimis, because 10 percent of the total assimilative capacity remains unused. In contrast, if the existing dissolved oxygen was 4.4 mg/L, then no increase in BOD could be de minimis because more than 90 percent of the total assimilative capacity would be utilized after the increase, i.e., the resulting dissolved oxygen would go below 4.4 mg/L.

3. Issues

During the GLWQI Technical Work Group discussions regarding the use of a de minimis test and the criteria that should define it, numerous issues were deliberated, and several alternatives considered. In addition to comments on the de minimis test laid out in the proposed Guidance, EPA solicits comments on the issues and decisions discussed below. Also, as discussed above, under C.2 "Significant Lowering of Water Quality", EPA is inviting comment on whether the use of the de minimis test should be extended to BCCs. EPA is interested in suggestions regarding any changes that should be made to the de minimis tests to address BCCs if such a change were made to the proposed Guidance.

a. *Use of Assimilative Capacity in De Minimis Decision.* EPA notes that the assimilative capacity described above is functionally the same as the loading capacity that is defined in the Federal

regulations at 40 CFR 130.2(f) and which forms the basis for total maximum daily load (TMDL) calculations. TMDLs are discussed in the implementation procedures section of this preamble. The technical analysis used to derive a TMDL may employ more sophisticated modelling techniques, but is intended to accomplish the same end as the determination of the assimilative capacity. EPA and the Great Lakes States decided to use the assimilative capacity instead of TMDL in the definition of a de minimis increase because of concerns regarding the regulatory approval requirements associated with formal TMDLs. TMDLs, including the derivation of the actual TMDL number and the decisions regarding allocation between point and nonpoint sources and margins of safety, receive formal EPA review and approval as part of the water quality management process. The State representatives on the Initiative Steering Committee were concerned that should the term TMDL be used in the de minimis definition, their ability to make decisions on potentially de minimis requests to lower water quality would be significantly delayed and diminished, but the basis for the de minimis decision would not be improved. In addition, TMDLs might not be conducted on the water bodies that might be subject to requests for lowering of water quality, since TMDLs are required only for the water quality limited segments identified by the States pursuant to 40 CFR 130.7(b), and water quality limited segments are prohibited from any degradation by the pollutant of concern under the proposed antidegradation standards. EPA requests comment on the proposed approach and the considerations discussed above.

b. *Fixing Assimilative Capacity at a Date Certain and Choice of Date.* The de minimis test in the proposed Guidance requires that the total assimilative capacity and the unused assimilative capacity be determined at the time the request to lower water quality is considered. The total assimilative capacity should remain relatively constant over time, changing only as the applicable criteria change or the critical low flow of the receiving water changes, for instance due to physical diversions or new flow data used to calculate the critical low flow. The unused assimilative capacity will be redefined each time a de minimis test is conducted and may increase or decrease due to, for instance, improvements in water quality, or increased uses of the waterbody, respectively.

EPA and the Great Lakes States chose the proposed de minimis procedure after consideration of a number of alternatives. One alternative considered would have required the States to determine the total assimilative capacity and the unused assimilative capacity on the date that the State antidegradation policy, as revised pursuant to the proposed Guidance and formally adopted into State standards, became effective. This approach would have required that States "fix" the assimilative capacity numbers in all Great Lakes System waterbodies in the State on a specific date, and all future requests to lower water quality would be considered against these numbers. As with the proposed approach, an action could be considered de minimis if it used less than 10 percent of that original unused assimilative capacity. In addition, at least 50 percent of the original unused assimilative capacity was required to remain after the lowering of water quality for the lowering to be considered de minimis.

Several concerns with this alternative led EPA not to propose it. First, there was concern that it would be logistically impossible for a State or Tribe to determine the unused assimilative capacity numbers for all applicable pollutants in all the Great Lakes System waterbodies on a single date. In addition, there were concerns expressed about the tracking required to determine when the cumulative effect of all actions that lowered water quality approached 50 percent of the initial unused assimilative capacity. Coupled with the questionable feasibility of this approach was the sense of the Work Group members that establishing the unused assimilative capacity at a date certain and then measuring all future changes against that figure would not accurately assess the significance of any given future action. Changes in the water quality that had occurred since the unused assimilative capacity was determined might not be reflected in the de minimis decision. In particular, improvements in the water quality, which might have led to larger mass load increases qualifying as de minimis, would not have played a role in this approach.

A second alternative considered by the Technical Work Group would have allowed the unused assimilative capacity to be established on the date of the first request to lower water quality on the segment of the waterbody affected. This alternative was intended to address the concern expressed about the first alternative regarding the feasibility of establishing the unused assimilative capacity for all non-BCC pollutants on all Great Lakes System waterbodies at the same time. Under the second alternative approach, the unused assimilative capacity for a particular waterbody would not be defined until an action was considered that might lower water quality. This would spread this workload out over a far greater time period than the first alternative, and perhaps eliminate the need altogether for such an evaluation of some waterbodies. An additional benefit that the Work Group perceived was that the amount and quality of the data used to define the unused assimilative capacity would likely be improved under the second alternative, as compared to the first. Nonetheless, the other disadvantages of the first alternative were not improved by the second. EPA requests comment on the proposed approach and the alternatives considered by the Work Group, and welcomes suggestions on other possible alternatives.

c. *Demonstration That No Ambient Change Occurs as a Result of Increased Loading.* Although not a part of the de minimis test, per se, the definition of significant lowering of water quality allows the Director to eliminate certain point and nonpoint actions that might involve increased mass loadings of non-BCCs from the antidegradation requirements where it is demonstrated to the satisfaction of the Director that the ambient concentration of the pollutant in the affected water body, outside of any applicable designated point source mixing zone, will not increase. The provisions further state that the Director may also take into consideration potential impacts on sediments and biota in the affected waterbody in reaching the decision.

EPA and the Great Lakes States decided to give the Director a mechanism, separate from the de minimis test, to exclude actions that would require an increased mass loading rate limit, but would not significantly lower water quality. For instance, a point source, which draws ground water as its process water supply, might consider a production increase that will require that it double its discharge flow rate, and, therefore, seek a doubling of the mass loading rate limit in its permit. The discharger might seek to prove that water quality is not significantly lowered by providing information for the pollutants involved regarding the projected concentration in the receiving water after allowable mixing. The Director might also request information on any potential effects on the sediments and biota, including those within the mixing zone where particulates might rapidly settle out of the discharge into the sediments. If the Director concludes, based on the

analysis of this and any other available information, that the increase in the mass loading rate limit on a non-BCC would not result in an increase in the ambient concentration of the pollutant, then the action may be considered not to significantly lower water quality.

EPA believes that by providing for such a demonstration, the number of antidegradation reviews, and the associated costs to the regulatory agency and the regulated public, will be reduced. More importantly, EPA does not believe that the environment will be adversely affected as a result of the proposed demonstration, because it does not apply to BCCs and it allows the Director to evaluate the potential points of accumulation of persistent substances when deciding if the action will have adverse effects. EPA is concerned that any increase in the rate of mass loading of a BCC has the potential to significantly lower water quality, because such substances accumulate in the biota, do not readily degrade, and often result in adverse effects at concentrations well below those that can be accurately measured in the ambient environment. In contrast, however, many of the other pollutants do not persist or bioaccumulate significantly. For these substances it may not be essential that an increase in the rate of mass loading be prevented in order for water quality to be maintained and protected. The demonstration provides information to the Director to make a decision on whether an increase in a mass loading limit for a substance other than a BCC changes the ambient water quality, and highlights areas such as sediment contamination that could reflect degradation and, depending on the chemical, should receive special attention.

EPA invites comment on this proposed provision and welcomes suggestions about how it might be improved. As discussed above, under C.2 "Significant Lowering of Water Quality", EPA is also inviting comment on whether the use of the de minimis test and the demonstration of no ambient change should be extended to BCCs. EPA is interested in suggestions regarding any changes that should be made to the demonstration of no ambient change to address BCCs if such a change were made to the proposed Guidance.

Proposed procedure 5 of appendix F to part 132 in the proposed Guidance establishes procedures to determine whether water quality-based effluent limits are necessary for NPDES permits (for discussion of this requirement see sections VIII.E and F of this preamble). The decision about whether or not limits are to be required in a permit is different than the decision, discussed above, regarding whether or not a proposed increase in a limit results in the significant lowering of water quality. EPA believes that the latter decision has no bearing on the former and that this element of the proposed Great Lakes Antidegradation Policy should not be used in a determination pursuant to proposed procedure 5 of appendix F.

d. *Use of the Margin of Safety Specified in the Implementation Procedures as a Ceiling on De Minimis Decisions.* For non-BCC pollutants on the GLWQI list of pollutants (i.e., those for which the implementation procedures are applicable), the proposed de minimis test relies on the implementation procedures margin of safety (MOS) provisions to prevent the allocation of virtually the entire unused assimilative capacity to any source or sources. The de minimis test only looks at the relative magnitude of the lowering of water quality resulting from any individual action in comparison to the unused assimilative capacity for the pollutant in question. Provided that the action uses no more than 10 percent of the unused assimilative capacity, it may be considered de minimis.

The MOS requirements provide an additional measure of safety to the process. The implementation procedures require that a portion of the TMDL (which is equivalent to the assimilative capacity) be set aside as a MOS and not allocated to any source. Although an action might be judged de minimis and exempted from the antidegradation demonstration requirements, the actual decision by the regulatory agency on the appropriate discharge limits would be made pursuant to the implementation procedures. An increase in the limits would only be allowed if an adequate MOS remained after the increase in the waste load allocation or load allocation and associated limits.

EPA considered building such a MOS provision directly into the de minimis decision, as it has for pollutants not covered by the implementation procedures. Specifically, one option considered for the de minimis procedure had included a requirement that at least 50 percent of the initial unused assimilative capacity remain after the lowering of water quality (in addition to the existing 10 percent increment requirement) for an action to be considered de minimis. This option was rejected by the Technical Work Group because it was considered redundant with the implementation procedures' MOS requirement. Additionally, the decision not to fix the unused assimilative capacity on a date certain (see discussion of previous issue) made the use of a 50 percent cap, as specified above, impracticable.

EPA has concerns about the reliance on the MOS requirements, which merit special attention and public comment. EPA is committed to the type of a cap that the MOS requirement in the antidegradation context would appear to provide, but is concerned that the MOS implementation procedure will provide limited coverage. In particular, the MOS implementation procedure is a part of the larger TMDL process. As described above under the first issue, "Use of Assimilative Capacity in De Minimis Decision," TMDLs are only required on a limited number of waterbodies, for a limited number of pollutants, and the particular conditions that would mandate a TMDL (i.e., a water quality limited segment) might eliminate the potential to allow any lowering of water quality. In essence, there is a good likelihood that the waterbodies with TMDLs will be the waterbodies for which a de minimis lowering of water quality is not available, and vice versa, the waterbodies for which de minimis is a meaningful test will not require TMDLs.

Where an MOS is defined, EPA requests comment on whether it establishes the cap at a level appropriate for a de minimis test. As discussed above, EPA and the Great Lakes States had considered a cap of 50 percent of the initial unused assimilative capacity as reasonable in the context of a de minimis decision. One TMDL/MOS alternative currently under consideration would establish the MOS at 25 or 75 percent of the TMDL, within the range considered acceptable for the de minimis test, and probably more protective than the figure of 50 percent of the unused assimilative capacity. However, another TMDL alternative in the proposed Guidance would allow the MOS to be virtually eliminated if the data supporting the TMDL are considered to be complete. EPA is concerned that the second alternative would not provide a reliable protective cap for the de minimis procedure.

EPA requests comment on these two issues regarding the use of the implementation procedures' MOS requirement, and, in particular, seeks advice on the need to directly incorporate a cap into the de minimis test rather than rely on an external process that may not always be available.

e. *Multiple De Minimis Lowering of Water Quality by a Single Source.* The de minimis test in the proposed Guidance does not restrict the number

of times that any individual source could seek an increase in permit limits for a non-BCC, and have that increase considered de minimis. The proposed Guidance simply looks at the effect of individual actions, not the source involved.

This has led to a concern that under the test, dischargers would try to get piecemeal approval of large projects by submitting multiple requests to lower water quality, each of which could be considered de minimis, but the net effect of which would be significant lowering of water quality. EPA believes that the procedure provides the Director with the discretion to prevent such abuse, but is nonetheless concerned that there could be considerable pressure brought on the Director to allow relief in individual cases.

EPA solicits comments on this concern. In particular, EPA is interested in whether commenters believe that it would be appropriate to limit the number of de minimis actions allowed any individual source to one (or some other number).

EPA also solicits comment on an approach that would address multiple lowering of water quality by different sources where the net effect is greater than 10 percent of the unused assimilative capacity. The approach proposed in this policy would potentially allow any individual action that uses less than 10 percent of the unused assimilative capacity to be considered de minimis, provided that the MOS requirement of the implementation procedures or the requirement in the definition of de minimis in section II.A of appendix E of the Great Lakes antidegradation policy was satisfied. During Work Group deliberations, EPA considered an alternate approach that would have assessed the cumulative effect of sequential actions when determining if the lowering of water quality used less than 10 percent of the unused assimilative capacity. For example, under such an approach, an action that utilized six percent of the unused assimilative capacity might be considered de minimis, while a subsequent action that utilized five percent of the unused assimilative capacity could not be considered de minimis, because the net effect of the two actions was greater than 10 percent of the unused assimilative capacity. The second action would be forced to go through a complete antidegradation review. However, subsequent actions would be evaluated against the unused assimilative capacity that would exist after the Director's antidegradation decision was implemented, with the potential for future de minimis lowering of water quality until such time as the next 10 percent increment was utilized.

EPA is not proposing this approach because of concerns regarding its implementation. EPA believes that the proposed de minimis requirements provide adequate protection of water quality. Further, the implementation of an approach such as that described above may place inequitable burdens on entities that propose to lower water quality, based not on the extent of degradation posed by any individual action, but rather as a result of the position in which it falls in a sequence of decisions. EPA believes that the assessment of multiple lowering of water quality is best addressed with the proposed MOS requirements and the proposed de minimis requirements of section II.A of appendix E of the proposed Guidance. The intent of these provisions in the proposed approach is to capture the effect of multiple actions by establishing a single point beyond which no individual action could be considered de minimis. EPA welcomes comment on this alternative approach to addressing multiple lowering of water quality, as well as the concerns noted above.

F. Antidegradation Demonstration Components

1. Background and Rationale

Both the Federal antidegradation policy and the antidegradation policy proposed in the proposed Guidance provide the regulatory agency with the opportunity to allow the lowering of water quality in HQWs, if it is found that "the lowering of water quality is necessary to accommodate important social and economic development in the area in which the waters are located." To date, EPA has provided little formal guidance on what it considers the specific tests that should be used or criteria that should be satisfied to demonstrate that a lowering of water quality meets this requirement. The proposed Great Lakes Guidance tries to strike a balance between the need to protect and maintain high quality water and the need to accommodate growth. The existing National policy requires this balance to be struck and the decision to be a public one. The tests established by the proposed Guidance are intended to be reasonable tools to accomplish that balance. EPA invites comments and suggestions on all aspects of the antidegradation demonstration and decision parts of the proposed Guidance to ensure they are reasonable.

As discussed during GLWQI Technical Work Group meetings, this part of the antidegradation policy, in particular, is viewed by the Great Lakes States and the regulated community as having a very high potential to lead to inconsistent decision-making between and even within States and Tribes. Two of the primary objectives of EPA and the Steering Committee in developing this antidegradation guidance were to provide an explicit description of the meaning of this requirement and an increased level of specificity regarding the appropriate tests and demonstrations to make such a showing.

The Great Lakes Antidegradation Guidance, in defining the demonstrations required to show that a lowering of water quality should be allowed, begins with a literal interpretation of the National regulation. That is, it interprets the phrase, "the lowering of water quality is necessary to accommodate important social and economic development in the area in which the waters are located" to mean that two types of demonstrations are required: one that shows that the lowering of water quality is necessary, or cannot be avoided, to support the development; and a second that shows that the development is important. EPA specifically invites comment on this interpretation of the existing National regulation. The two types of demonstrations are defined under the Antidegradation Demonstration heading in the proposed Guidance (section III of appendix E to part 132), and the requirements for the incorporation of the results of the demonstrations into water quality decisions are found under the heading Antidegradation Decision (section IV of appendix E to part 132).

The Antidegradation Demonstration section of the proposed Guidance identifies two broad categories that will be required of an entity to make the "necessary" component of the demonstration: information to show how prudent and feasible pollution prevention alternatives might be implemented to eliminate or reduce the extent to which water quality is significantly lowered (section III.A of appendix E to part 132); and information to show what alternative or enhanced treatment exists that would eliminate the significant lowering of water quality and what it costs in comparison to the cost of "normal" pollution control (section III.B of appendix E to part 132). Each of these is discussed in detail below.

The Antidegradation Demonstration section also identifies information that will be required of an entity that is seeking to significantly lower water

quality in order to show that the lowering supports "important social or economic development" (section III.D of appendix E of the proposed Guidance). Five broad categories of social or economic developments, which are considered important, are identified. This demonstration, too, is described in detail below and under a separate subsequent heading in this preamble.

2. Hierarchy of Antidegradation Demonstrations

A hierarchy is established for the demonstrations in the proposed Guidance that is not only a logical sequence but also reflects a priority of EPA. As laid out in the proposed Guidance, the first tier in the hierarchy is the pollution prevention alternatives analysis: successful implementation of such alternatives to eliminate the significant lowering of water quality relieves the entity of the requirement to supply additional information regarding alternative or enhanced treatment and the social or economic development provided by the action. EPA believes it is appropriate to require that an entity provide information that the Director will use to determine if the lowering of water quality is necessary, i.e., cannot be prevented while still accommodating the action, before it is required to demonstrate that the action is an important social or economic development or is critical to the support of such development. Furthermore, EPA and the Great Lakes Steering Committee place a very high priority on the application of pollution prevention techniques as the preferred approach to prevent or reduce the significant lowering of water quality. Consequently, the first demonstration evaluates the extent to which prudent and feasible pollution prevention alternatives reduce or eliminate the significant lowering of water quality that would otherwise accompany the development. In assessing prudent and feasible alternatives, EPA believes that it will be appropriate to compare the unit cost (dollars per toxic pound equivalent) of removing a pollutant or type of pollutant using the pollution prevention alternatives under consideration with benchmark control estimates. As a benchmark for such a comparison, EPA is considering the unit cost estimates ($1.30 to $10.40 per toxic pound equivalent) developed for source categories as a part of this rulemaking or, alternatively, the incremental cost estimates developed as a part of EPA's effluent guidelines for source categories ($1 to $500 per toxic pound equivalent). The details of this demonstration are discussed under section F.3 of this preamble.

The proposed Guidance directs the regulatory agency to require the implementation of prudent and feasible pollution prevention alternatives as a precondition to the lowering of water quality. If the implementation of such alternatives would eliminate the need to significantly lower water quality, no further demonstrations are required, the facility may proceed (with the pollution prevention measures in place), and appropriate control requirements are established in the control document to ensure that water quality is not significantly lowered. If prudent and feasible pollution prevention alternatives do not eliminate the lowering of water quality, but do reduce the extent to which the water quality is significantly lowered, the Director will establish conditions in the control document that, at a minimum, ensure that water quality is not lowered any more than it would be if the prudent and feasible pollution prevention alternatives were implemented, and which may be more stringent depending on the results of the other evaluations in this section.

The second tier in the hierarchy requires the evaluation of alternative or enhanced treatment techniques to determine the cost to the entity of providing additional or different treatment to eliminate the significant lowering of water quality. Again, EPA believes it is appropriate to require that an entity provide information for the Director to use to determine if the lowering of water quality is necessary before it is required to provide information for the Director to use to determine if the action is an important social or economic development or is critical to the support of such development. This tier represents a second type of information that the Director may use to determine if the significant lowering of water quality is necessary. This evaluation builds on the results of the first: if prudent and feasible pollution prevention alternatives could eliminate a portion of the significant lowering of water quality, i.e., reduce the amount by which the rate of mass loading of a pollutant must be increased to accommodate the action, then the evaluation of alternative or enhanced treatment techniques should be applied to the remaining increase in loading. (As an example, if a proposed action initially would have required an increase in the rate of mass loading of a pollutant of 100 pounds per day, and the implementation of prudent and feasible pollution prevention alternatives drops that increase to 50 pounds per day, then the evaluation of alternative or enhanced treatment should, generally, only look at the cost of eliminating the remaining 50 pounds per day.) The cost (capital and operation and maintenance) of the alternative or enhanced treatment is compared to the comparable cost of the treatment required to meet technology- or water quality-based requirements or requirements based on other State or Federal standards and, where the ratio is less than or equal to 1.1 to one, the lowering of water quality is not considered "necessary" and there is no need to consider information on the social or economic development that the proposed significant lowering of water quality would have supported. Instead, as the Antidegradation Decision provision of section IV.A.2 of appendix E to part 132 requires, the significant lowering of water quality is not allowed, and either the permitted discharge levels remain unchanged or the appropriate control requirements are established in the control document to ensure that water quality is not significantly lowered. As an alternative, EPA is requesting comments on a cost effectiveness approach using a comparison of the control costs (per toxic pound equivalent) of the enhanced treatment with baseline control costs (per toxic pound equivalent). When control costs for the enhanced treatment are no greater than the baseline costs, facilities would be expected to adopt the enhanced treatment techniques. The details of the second demonstration are discussed in section F.4 of this preamble.

There may be occasions when it is more cost effective to simply provide alternative or enhanced treatment to eliminate the significant lowering of water quality, rather than to couple such treatment with pollution prevention techniques, and a discharger may propose that treatment alone be used to eliminate the significant lowering of water quality. In reaching such a decision, EPA anticipates that the discharger would have evaluated the benefits of the available pollution prevention alternative, such as the reduction in cross-media pollutant transfers and any associated regulation under other environmental statutes. This proposed Guidance provides the flexibility for the Director to accommodate those situations, with the objective of finding the most appropriate means of eliminating the significant lowering of water quality, where possible. EPA, however, believes that in the majority of situations, the prudent and feasible pollution

prevention alternatives will complement the alternative or enhanced treatment techniques, and that the most effective mechanism to prevent the significant lowering of water quality will be a combination of the two.

The third tier of the hierarchy is the demonstration that the significant lowering of water quality is critical to important social and economic development. To have reached this point in the process, the Director would have been given information on the ability of the entity to prevent the significant lowering of water quality and that information would have shown that the significant lowering of water quality could not be prevented by the application of prudent and feasible pollution prevention alternatives in combination with alternative or enhanced treatment that is available within a defined cost range. The proposed Guidance requires the entity to demonstrate how a decision not to allow the significant lowering of water quality, i.e., disapproval of the proposed significant lowering of water quality, will prevent important social or economic development in the area in which the waters are located. The proposed Guidance lays out five broad areas of social or economic development, which would be considered "important". These are discussed in detail in section F.5 of this preamble. If the significant lowering of water quality is critical to a development in any one of these areas, the Director may tentatively approve it, subject to public comment and intergovernmental coordination.

3. Identification of Prudent and Feasible Pollution Prevention Alternatives To Prevent or Reduce the Significant Lowering of Water Quality

The pollution prevention alternatives analysis section of the proposed Guidance, section III.A of appendix E to part 132, identifies five categories of alternatives that must be evaluated by an entity seeking to significantly lower water quality. They are as follows:

a. *Substitution of BCCs with Non-bioaccumulative and/or Non-toxic Substances.* The primary objective of this evaluation is to determine if the source of a BCC, which would otherwise be causing or contributing to a significant lowering of water quality, can be eliminated in favor of a less environmentally problematic substance, for example a substance that is not a BCC;

b. *Application of Water Conservation Methods.* This evaluation considers whether the introduction of water conservation methods by a discharger is feasible and, if so, whether their implementation would prevent or reduce the significant lowering of water quality;

c. *Waste Source Reductions Within Process Streams.* Certain production processes may have the potential to be "fine-tuned", but have not been because of a lack of any compelling reason to attempt to do so in the past. This evaluation would look at the potential for such fine tuning to relieve the need to significantly lower water quality;

d. *Recycle/Reuse of Waste Byproducts, Either Liquid, Solid, or Gaseous.* Internal recycling/reuse of waste streams is a common practice in many industrial and manufacturing processes to hold down energy, raw materials, and waste disposal costs. This evaluation would consider whether additional or new recycling/reuse operations are available that would relieve the need to significantly lower water quality; and

e. *Manufacturing Process Operational Changes.* This evaluation would consider the alternatives to a particular industrial or manufacturing process that are available to the entity that seeks to significantly lower water quality. For many operations, a variety of processes exist to reach the same end product, or one that is within set tolerance limits. The specific operation should be evaluated and any available, acceptable alternatives that would relieve the significant lowering of water quality identified.

The categories of pollution prevention information identified in the proposed Guidance are intended to be interpreted broadly so as to provide for consideration of a wide range of possible alternatives. Furthermore, it may well be appropriate for the Director to consider a combination of alternatives from several categories operating in conjunction. The categories provide a guideline on the minimum coverage of a pollution prevention evaluation for entities that seek authorization to significantly lower water quality. In addition, nothing in this demonstration requirement bars the Director from requesting pollution prevention alternatives information as the Director might deem necessary to evaluate the request to significantly lower water quality. The authorities to request the pollution prevention information outlined in the proposed Guidance, and any additional information the Director deems necessary to make the evaluation, derive from the same statutory provisions as other information requests under the NPDES and nonpoint source programs. An entity that is pursuing authorization to significantly lower water quality should consult with the appropriate regulatory authority to determine the specific alternatives that it will be expected to evaluate.

The following provides brief examples of alternatives that would be appropriate for consideration in the context of, first, an industrial point source and, second, a municipality, using the category "substitution of BCCs with non-bioaccumulative and/or non-toxic substances". Depending on the context, BCCs may be used as, or present in, raw materials in production processes, in consumer products, and in a variety of other ways.

The scope of alternatives evaluated will vary according to the source. For example, a coal fired power plant seeking to increase its generating capacity might be faced with the prospect of a larger coal pile and an increased amount of mercury contaminated runoff. The alternatives that should be evaluated in such a situation, to reduce the loading of mercury from coal pile runoff, would include use of an alternative supply of coal containing less mercury as a trace contaminant. The substitution of a "cleaner" coal supply would have the added benefit of reducing air emissions of mercury, which would also help to maintain and protect water quality. The information provided by the power plant would include the effectiveness of the alternative source with regard to reduction in the rate of mass loading of mercury, differential (greater or lesser) cost associated with the new coal source, impediments to using the alternate coal or its source (supplier), and other environmental effects (positive or negative), as the Director deems necessary to determine if the alternative is prudent and feasible.

As another example, a municipality, which has a mercury mass loading limit in its NPDES permit, that is considering expansion of the sewer service area, and requests a corresponding increase in the wastewater flow and mass loading limitations, would have a number of potential alternatives to limit the source of mercury discharges to its sewers. A ban on the introduction of mercury into the sewer system, coupled with a strong public education program emphasizing the problems with, for example, broken mercury thermometers, the contents of which are flushed down the toilet, or mercury-containing exterior latex paint cleanup in the kitchen sink, might be a particularly viable alternative. The municipality should also consider the effectiveness of working back to its industrial users to identify and eliminate mercury sources using its

sewer use ordinance and inspections to ensure compliance. The same type of information as was discussed in the power plant example above would be provided to assist the Director in determining if such alternatives are prudent and feasible.

The proposed Guidance does not specify criteria to be used by the Director to determine what is "prudent and feasible." The decision that an alternative or combination of alternatives is prudent and feasible is the decision of the Director, and not the entity that is seeking to significantly lower water quality. States and Tribes are encouraged to develop their own guidelines to follow when evaluating pollution prevention alternatives identified by the entity to select those that are prudent and feasible. EPA believes that in making this determination it will be appropriate to compare the control costs implicit to the pollution prevention alternative with benchmark control costs. EPA requests comments on the merits of this approach and suggested alternatives that might be used to inform this decision.

Concerns were expressed during deliberations on the proposed Guidance that the determination of what constitutes prudent and feasible pollution prevention alternatives could involve multiple iterations of demonstrations by the regulated entity. In particular, there was a concern that the proposed Guidance does not itself specify the information needs for a satisfactory demonstration nor does it require that the needs be articulated definitively by the regulatory agency at the outset. Furthermore, the proposed Guidance does not place constraints on the regulatory agency's ability to require multiple demonstrations by an entity until it provides information that the Director considers satisfactory. EPA acknowledges that the language in the proposed Guidance does not provide specific guidance on how the Director makes a determination of what is prudent and feasible. EPA requests comment on the need for establishing more specific criteria for this determination.

EPA expects that in implementing the prudent and feasible criterion the regulatory agency and that the regulatory agency will not abuse the criterion to simply delay projects through multiple iterations of information requests. As discussed above, EPA anticipates that the States will develop guidance to assist in this case-by-case decision-making. Nonetheless, EPA recognizes that there may be instances in which the regulatory agency requires additional information, beyond that anticipated in an initial request, to make a decision on prudent and feasible pollution prevention techniques. While the regulatory agency should seek to develop guidance to limit such instances, it should not be compelled to make decisions on an inadequate demonstration.

EPA specifically requests comment on the use of "prudent and feasible" as the criterion upon which pollution prevention alternatives are evaluated and chosen by the Director. EPA is interested in whether the proposed Guidance provides the correct level of detail to assist in this decision, and if not, what additional detail commenters feel should be incorporated. While the proposed Guidance does not explicitly require cost/benefit or cost effectiveness analyses, in determining what is prudent and feasible EPA believes that the Director will likely weigh the cost of the pollution prevention measures against the benefits with regard to the reductions in pollutant loading. EPA requests comment about whether a formal cost/benefit analysis or a cost effectiveness analysis with defined decision criteria should be part of the prudent and feasible decision. As regards decision criteria for a cost effectiveness analysis, EPA believes that it may be appropriate to compare the unit cost (dollars per pound equivalent) of removing a pollutant or type of pollutant using the pollution prevention alternative under consideration with unit cost estimates developed for this rulemaking ($1.30 to $10.40 per toxic pound equivalent) to reach a decision. Alternatively, the incremental unit costs associated with implementation of a particular pollution prevention alternative could be compared to the incremental costs used in EPA's effluent guidelines for a comparable industrial category ($1 to $500 per toxic pound equivalent for a waste stream). In either case, where such a comparison showed that a pollution prevention alternative could remove an equivalent amount of a pollutant or pollutants at no greater cost, that alternative could be considered feasible. EPA requests comment on these possible approaches to assessing cost effectiveness. EPA would also welcome examples of alternative criteria that have been effectively employed by commenters in similar decision-making situations.

4. Alternative or Enhanced Treatment Alternatives That Eliminate the Significant Lowering of Water Quality

Section III.B of appendix E of the proposed Guidance requires that an entity seeking to significantly lower water quality (and not able to identify prudent and feasible pollution prevention alternatives that eliminate the need to significantly lower water quality) provide information on the alternative or enhanced treatment techniques that could be utilized to treat its waste stream and that eliminate the need to significantly lower water quality. Put another way, the entity has to tell the Director what it would cost for treatment to maintain the status quo in terms of effluent quality for BCCs and effluent limits for other pollutants, and what that treatment would entail. In addition to the information on alternative or enhanced treatment, the entity must provide comparable information on the treatment that would be required to comply with the revised effluent limits that it is seeking. These revised limits would be defined by the applicable Federal effluent guidelines, State water quality standards (other than antidegradation), and other applicable State or Federal standards.

The cost information provided for this demonstration will include both total capital costs of treatment facilities and the operation and maintenance costs associated with running them. Cost information must be provided for the least costly alternative that eliminates the significant lowering of water quality. Cost information must also be provided for the treatment system that would be required to meet the revised (increased) limits. The costs information developed for the two scenarios must be comparable. That is, the assumptions used in one scenario (e.g., depreciation factor, useful life, constant dollars) must be consistent with those used in the other. Furthermore, the capital cost information should incorporate the capital cost of the existing treatment facility if it will be utilized in the treatment train to meet the revised limits or to eliminate the need to significantly lower water quality, rather than only the incremental costs of additional treatment, or alternative or enhanced treatment. In addition, the costs of the prudent and feasible pollution prevention techniques are not included in the costs of alternative or enhanced treatment, but rather factor into the base costs against which the cost of alternative or enhanced treatment is compared.

EPA requests comment on the benchmark costs used in the proposed analysis. In the approach described above, the entire capital expenditures over the life of a facility would be used. This could be argued to have the effect of "punishing" an entity that had spent large amounts on a treatment system in the past. EPA is particularly interested

in whether commenters believe that it is more appropriate to use only a portion of the total capital costs of a treatment system (e.g., the capital expenditures during the last permit term, or the capital expenditures that will be necessary to comply with any new limits that will derive from other parts of the proposed Guidance) in such an analysis.

The proposed Guidance requires that the total costs to eliminate the significant lowering of water quality be compared to the total costs to comply with the requested revised permit limits. If the ratio of the costs is less than or equal to 1.1 to one, i.e., if up to a 10 percent increase in the cost of treatment over what will otherwise be required will eliminate the significant lowering of water quality, then the entity will be expected to utilize the additional treatment to prevent the significant lowering of water quality. The control document issued to the entity will not allow an increase of mass loading limits, or in the rate of mass loading of a BCC. In such cases, since the action no longer necessitates the significant lowering of water quality, the entity no longer needs to provide information to show that important social or economic development is supported. If, however, the additional 10 percent expenditure for alternative or enhanced treatment will not eliminate the significant lowering of water quality, the entity must provide social or economic development information to support the continuing request to significantly lower water quality.

EPA emphasizes that the Alternative or Enhanced Treatment test establishes a mandatory expenditure provision which identifies the minimum that will be expected of an entity seeking to significantly lower water quality and the condition under which it is effective. This proposed Guidance reflects the priority of EPA and the Steering Committee to protect and maintain the quality of the water in the Great Lakes System. It establishes a minimum level of expenditures that must be made on treatment if it prevents the significant lowering of water quality. It does not mean that the significant lowering of water quality will automatically be approved if that minimum level of expenditure does not prevent the significant lowering of water quality.

The mandatory minimum expenditure established by this provision reflects a policy position of EPA and the GLWQI Steering Committee regarding the value of maintaining and protecting water quality in the Great Lakes System. While it reflects the value attached to the Great Lakes, it does not represent a formal cost/benefit analysis by EPA or the GLWQI Steering Committee. The GLWQI Steering Committee was particularly concerned that a numeric minimum guideline be established for this test to promote consistent decision making among the Great Lakes States and Tribes. EPA requests comment on the ratio that is proposed to establish this minimum cost requirement, whether it is set at the appropriate level, and whether a single ratio should be identified or various ratios depending on the entity (public or private). Commenters are encouraged to provide specific examples of alternative provisions that EPA might consider and are referred to another set of tests described later in this preamble as a possible alternative for which EPA is also requesting comment. EPA also solicits comment on whether the proposed Guidance should rely on a cost/benefit analysis to establish the appropriate ratio, or whether the proposed Guidance should propose the use of cost/benefit analyses on a case-by-case basis to determine mandatory expenditures on alternative or enhanced treatment to prevent the significant lowering of water quality.

Finally, EPA requests comment on an alternative that would compare the control costs (per pound of toxic equivalents) of alternative or enhanced treatment techniques with a benchmark estimate of control costs—that is, evaluate the cost effectiveness of these enhanced treatment alternatives. EPA might use as a benchmark the control cost estimates for comparable source categories developed under the effluent guidelines program or the control cost estimates EPA is developing as a part of this rulemaking. Thus, if the cost of control (per pound of toxic equivalent) for an identified enhanced treatment technique were no more than the benchmark control cost (per pound of toxic equivalent), this treatment technique would be considered to be available and this treatment level would be expected to be adopted as a part of the antidegradation demonstration. Otherwise the enhanced treatment would be considered unavailable.

EPA considered the following text for inclusion in the rule in place of that currently found in the last two sentences of proposed section III.B of appendix E to part 132:

> The evaluation shall compare the control costs (per pound of toxic equivalent) of such alternative or enhanced treatment with the benchmark control cost estimates for source categories. (See control cost estimates set out in Table X [table would be developed for inclusion in rule].) If the control cost (per pound of toxic equivalent) is no greater than the benchmark control cost, the entity shall not be required to provide the information specified in section III.D.

A similar conforming change would also be made to section IV.A.2 of appendix E of the proposed rule.

An important advantage of this approach would be that it combines the cost of the enhanced treatment techniques with a measure of its effectiveness. EPA believes that, in considering effectiveness as well as cost, this may represent an improvement over the proposed approach. The proposed approach establishes an arbitrary requirement that future costs of an enhanced treatment technique should not exceed 1.1 times the past sunk cost of existing treatment controls, and requires the enhanced treatment only if it is completely effective at eliminating the increased loading of pollutants (i.e., 100 percent effective). The 1.1 to one ratio may be too low for very large reductions in loadings and too high for very small reductions in loadings.

EPA requests comments on the alternative cost-effectiveness approach. In particular, EPA is interested in comments on the use of a benchmark control cost based on unit cost estimates developed for source categories as a part of this rulemaking ($1.30 to $10.40 per toxic pound equivalent). Alternatively, the benchmark could be based on the incremental cost estimates developed as a part of EPA's effluent guidelines for individual source categories ($1 to $500 per toxic pound equivalent for a wastestream). EPA also requests comments on the appropriate ratio to use in comparing the costs of an enhanced treatment technique with baseline control costs. The above discussion assumes a ratio of one-to-one (i.e., the enhanced treatment cost is no more than the baseline cost, per toxic pound equivalent), but EPA is interested in whether commenters feel the ratio should be greater, for example 1.3 to one, which would result in enhanced treatment being required if it costs no more than 1.3 times the baseline cost of control (per pound of toxic equivalent).

This provision does not constrain the Director from requiring more costly treatment to eliminate the significant lowering of water quality, nor does it prevent the Director from requiring that the alternative or enhanced treatment be implemented in cases where it does not fully eliminate the need to significantly lower water quality. However, such decisions are the best professional judgment of the Director, and are not dictated by this proposed Guidance.

Furthermore, this provision must not be construed to have any bearing on the ability of EPA or the States or Tribes to

seek appropriate relief for the violation of NPDES permit limitations or other enforceable requirements, up to and including the maximum amounts available under the applicable statute. This provision is relevant only in the permitting process for the purposes of antidegradation decisions. It does not apply in the compliance context. The cost of complying with the terms and conditions of a permit does not excuse non-compliance. The lowering of water quality is never allowed when it would cause water quality standards to be exceeded. In the enforcement context, EPA conducts an "ability to pay" analysis which is a complex calculation of the economic impact of compliance and payment of civil penalties on the members of the regulated community. "Affordability", as it might be considered in the context of an antidegradation decision, is not considered in either a penalty analysis or an ability to pay calculation. In the penalty context, an ability to pay calculation is not a determination of affordability; penalties are a deterrent and are not designed to be affordable as a cost of doing business. Rather, in considering ability to pay, EPA considers a violator's inability to continue in business after achieving compliance and paying a civil penalty. Compliance with the law is the minimum requirement in the enforcement context. EPA requests comment on whether the proposed Guidance is sufficiently clear on these points or if additional detail is warranted.

EPA also solicits comments on whether the alternative or enhanced treatment analysis should include, in addition to such cost considerations, consideration of relative energy consumption, air emissions, and other non-water quality impacts.

5. Social or Economic Development Demonstration

Section III.D of appendix E of the proposed Guidance defines the requirements for a demonstration that the necessary significant lowering of water quality supports important social or economic development in the area in which the waters are located. To have reached this point in the process, the Director would have been given information on the ability of the entity to prevent the significant lowering of water quality and would have determined that information showed that the significant lowering of water quality could not be prevented by the application of prudent and feasible pollution prevention alternatives in combination with alternative or enhanced treatment that is available within a defined cost range. Then, the social or economic development demonstration is conducted to show how the development is important to the community in the area in which the waters are located in terms of employment, financial, or social services contributions.

Defining the area in which the waters are located is a case-by-case determination by the Director that may consider the pollutants involved in addition to the location of the discharge. The benefits of a development, which would cause it to be considered important in an antidegradation decision, should be those realized within the area in which the waters are located, as opposed to outside of the area in which the waters are located. EPA requests comments on how broadly the area in which the waters are located should be defined. For example, should the area be limited to the close proximity of a discharge, the entire Great Lakes System, or some intermediate, and should the decision depend on the type of pollutant involved?

The analyses used by the regulatory agency under this provision measure the amount of social and economic gain, or loss prevented, in the area in which water quality is proposed to be significantly lowered and assess the environmental effects due to the action proposed. Information on the following areas of social or economic development resulting from the action that results in the significant lowering of water quality are to be provided by the entity proposing the action: increase in number of jobs; increase in personal income and/or wages; reduction in unemployment rate or social service expenses; increase in tax revenues; and provision of necessary social services. Each of these should be examined in terms of both the absolute size and the relative size of the change.

In evaluating the changes in any of these five types of factors, as well as the environmental effects, logically three references should be established: the baseline situation, the net impact, and other possible developments.

a. *Baseline Situation.* Once the area has been defined, its baseline condition should be evaluated in terms of its unemployment rates, percentage of the population living on incomes below the poverty line, percent of population that are elderly, and average household income compared to state or national averages and any other information requested by the Director. Additional jobs and/or tax revenues are particularly important to economically-depressed areas.

b. *Net Positive Impact.* The net impact is relevant in measuring the importance of the development. It is determined by correcting the amount of benefits to account for any adverse impacts that result from the development, such as the loss of tourism income if the lowering of water quality reduces the recreational opportunities, or the increase in operating costs of other facilities that use the water and any other information requested by the Director.

c. *Other Developments.* In determining if a particular development is important, the Director should consider whether other developments of comparable contribution will occur in place of this particular one.

The proposed Guidance provides no numeric benchmarks against which social and economic developments are measured to determine if they are important. Rather, provided that the developments fall into one of the above categories, which EPA and the Steering Committee agree are inherent benchmarks of importance, the final decision on whether they justify the significant lowering of water quality is left to the discretion of the Director, taking into account the specific characteristics of the pollutants involved, the affected community, and the comments of the public. It is in the context of making this decision that the Director may require additional controls beyond those mandated by the pollution prevention alternatives and alternative or enhanced treatment analyses, to restrict or prevent the lowering of water quality.

EPA encourages comment on this element of the proposed Guidance, and, in particular, on whether it provides sufficient detail to assist the Great Lakes States and Tribes in making consistent decisions.

6. Special Remedial Action Provision

Section III.E of appendix E of the proposed Guidance provides a special antidegradation provision for remedial actions that are not otherwise exempted from the definition of significant lowering of water quality. Remedial actions subject to this provision would include those implemented pursuant to State or Federal authorities, such as the Resource Conservation and Recovery Act (RCRA) or CERCLA, with the purpose of cleaning up environmental contamination. Such actions do not lend themselves to the evaluations discussed above, involving alternative or enhanced treatment or social or economic development. Accordingly,

EPA believes that an alternative test should be used to establish that a significant lowering of water quality is necessary to accommodate important social or economic development. Such an alternative is established by this provision.

Under section III.E of appendix E of the proposed Guidance, entities proposing remedial actions submit information to the Director that demonstrates that the action utilizes the most cost effective pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through D of appendix E of the Antidegradation Demonstration portion of the proposed Guidance (covering alternative or enhanced treatment analysis, Lake Superior special provision for Outstanding International Resource Waters, and important social or economic development demonstration). The decision on what constitutes the most cost effective pollution prevention and treatment techniques available and whether the lowering of water quality is minimized through the implementation of such techniques is left for the Director to make on a case-by-case basis using best professional judgement.

EPA believes that such remedial actions may be generally considered to be in the public interest, because they are implemented to protect public health and welfare and the environment. Consequently, it would be redundant to require a showing that a remedial action is critical for important social or economic development. EPA welcomes comment on this position and on the requirements of this provision, in general.

7. Issues

a. *Other Options Considered for Determining if Significant Lowering of Water Quality is Necessary.* EPA believes that the proposed prudent and feasible pollution prevention and alternative or enhanced treatment techniques demonstrations, as described above, are the most appropriate and functional options of those considered. However, several other approaches were considered during the development of the Great Lakes Antidegradation Guidance. One other approach considered at length focussed on explicitly defined economic tests as a measure of whether the significant lowering of water quality is necessary. This type of "affordability" approach is discussed below, with an emphasis on how it differs from the proposed approach.

The affordability approaches are typified in that they define benchmark criteria based on specific economic measures, to be used in determining if the significant lowering of water quality is allowable. The affordability approach considered during the Work Group deliberations provided a criterion, based on the cost of a facility expansion or new development, to define the mandatory costs to be expended on pollution control to prevent or reduce significant lowering of water quality. In addition, the affordability approach defined a second benchmark criterion based on the financial health of a facility or municipality that would be used to determine if additional pollution control expenditures, beyond those identified as mandatory, were affordable. Such affordable expenditures, and the improvements in discharge quality associated with them, would be required by the Director. Should such expenditures eliminate the significant lowering of water quality, the lowering would not be considered necessary, and would not be approved. A representative example of the affordability approach would contain the following elements.

First, the affordability approach would require that the entity submit information on pollution prevention alternatives and treatment techniques that are available to the entity and would eliminate or reduce the significant lowering of water quality. The information submitted would include the cost of such measures and their effectiveness in removing the pollutants associated with the proposed significant lowering of water quality, along with specific information on the financial health of the entity and the cost of the expansion or development that was proposed to significantly lower water quality.

The Director would then conduct a two-part analysis of this information. First, the information would be used to identify mandatory control expenditures, i.e., identify a specific dollar amount that must be spent by the entity to reduce or eliminate the significant lowering of water quality. EPA considered defining the mandatory expenditure amount in terms of a specific ratio between the annualized pollution control cost (capital and operation and maintenance costs) and the total capital cost of the expansion or development that would be responsible for the significant lowering of water quality. The analysis would then identify alternatives that are available within the defined cost range and the extent to which the significant lowering of water quality will be reduced by each alternative. The Director would be required to direct the entity to implement the most effective alternative by establishing control requirements, such as NPDES permit limits, at the pollutant mass loading rate achieved by the control alternative. If any alternative was completely effective at preventing the significant lowering of water quality, then the existing control requirements would be maintained or new requirements established to prevent the significant lowering of water quality, i.e., at existing mass loading rates.

If the mandatory pollution control expenditures did not eliminate the significant lowering of water quality, a second analysis of the submitted information would be conducted to identify any additional amount that the entity could afford to spend on pollution controls, in addition to the mandatory control expenditures. EPA considered defining the affordable amount in terms of a specific ratio between the annualized pollution control cost and the annual revenues for the entire establishment for private entities.

Similarly, EPA considered a factor based on the household burden to define affordable expenditures for public entities. The analysis would identify the controls that are available for that affordable amount and the extent to which each would lessen the significant lowering of water quality. The entity would be required to undertake additional expenditures within the defined affordable cost range. If significant lowering of water quality was eliminated within this range, then control requirements would be established to maintain water quality; otherwise, control requirements would be established that reflect the most effective of the alternatives available within the defined affordable cost range.

The key differences between the proposed approach and the affordability approach discussed above are as follows:

i. Unlike the proposed approach, the alternative pollution prevention and alternatives analysis in the affordability approach has no reference to prudent and feasible as a criterion for the Director's decision, nor is this analysis limited to pollution prevention alternatives: it also requires information at this stage on treatment alternatives. In the affordability approach, this step is simply a broad information gathering requirement.

ii. The mandatory pollution control expenditures part of the affordability approach is similar to the alternative or enhanced treatment provision in the proposed Guidance in that they both

establish mandatory expenditure requirements, but they differ in several significant respects. First, the affordability approach would evaluate all types of control alternatives, including treatment and pollution prevention, whereas the parallel provision in the proposed approach would only evaluate treatment alternatives. Second, the cost ratios used by the two tests are fundamentally different. The affordability approach would have established a cost figure based on the size of the expansion or development that is causing the significant lowering of water quality, whereas the proposed approach sets a cost figure based on the treatment expenditures to meet minimum state and federal discharge requirements. Third, the affordability approach would have mandated the expenditure of the identified amount regardless of the effectiveness of the alternatives. That is, the most effective alternative available at the identified cost would have been required to be implemented, even if it would not have completely eliminated the significant lowering of water quality, but instead only reduced the extent to which water quality was significantly lowered. In contrast, the proposed approach mandates the implementation of alternative or enhanced treatment techniques only when they are effective at eliminating the significant lowering of water quality. As discussed earlier, the Director may require expenditures that are not mandated by this provision in the proposed Guidance, but does so on a case-by-case basis. EPA requests comment on whether or not it is appropriate to require facilities to make expenditures of a threshold amount even if the expenditure does not fully eliminate the lowering of water quality.

iii. The additional affordable pollution control expenditures analysis in the affordability approach would require that information be provided to the Director to be used to identify any pollution control options, beyond those identified as mandatory, that must be required of the entity, because they are "affordable". It would lay out a cost formula to be used to define how much is affordable. In contrast, the proposed Guidance leaves such decisions regarding affordability to the discretion of the Director. Presumably, a component of the prudent and feasible pollution prevention alternatives decision will involve an assessment of affordability that will look at the ability of the entity to pay for the alternatives. Similarly, the final decision on controls that might be required when there are no identified mandatory alternative or enhanced treatment techniques will likely involve an affordability analysis component. However, the proposed Guidance leaves the use of affordability analyses and the criteria for determining what is affordable to the Director's discretion.

Various models could be constructed to determine "affordability" in the context of either approach. For instance, in the enforcement context, EPA utilizes models to determine a violator's inability to continue in business after achieving compliance and paying a civil penalty. For example, one of these models, "ABEL", assists in evaluating the financial health of for-profit entities. (In the context of an enforcement decision, EPA and the States consider many other factors in addition to the results of these models. Some of these other factors include the magnitude of the violation, the degree of environmental damage, the entity's recalcitrance, and the extent of the entity's cooperation.)

Based primarily on a determination of solvency, such models might provide a partial basis for an affordability model suitable for making antidegradation decisions. EPA does not suggest that such models, in and of themselves, provide results sufficient for making antidegradation decisions. These tools, however, can identify entities that might have financial difficulty funding additional controls. Additional financial analyses must complement the model results to arrive at a satisfactory conclusion. EPA requests comments about the suitability of these or other relevant models as screening devices to determine which entities might require more in-depth analysis.

In addition, as mentioned above, some regulatory agencies may already employ various methods of determining "affordability" in the context of their regulatory activities. EPA requests comment on the experience of regulatory agencies in applying these tests, including a detailed description of the context in which they are employed and the agency resources necessary to carry them out.

Several concerns prompted EPA to propose the approach in the proposed Guidance instead of an affordability approach. These concerns are discussed below, along with requests for comment on specific related issues.

The first issue is the difference in the degree of flexibility granted to the Director. The proposed approach provides the Director much discretion in identifying what other expenditures should be required in the event that the mandatory expenditures do not prevent the significant lowering of water quality. The proposed approach focusses on controls that result from prudent and feasible pollution prevention alternatives, but allows for a variety of additional considerations in the final decision.

The affordability approach would have provided very specific criteria for determining which costs are affordable and, therefore, must be implemented. The affordability approach was intended to represent an analytically simple and straightforward procedure for evaluating whether the lowering of water quality is necessary. However, with each of the simplifying steps involved, some degree of accuracy was lost. Thus, the procedures required qualifications, and do not take many site-specific factors into account.

EPA is concerned that, in light of the above qualifications, the benefits in consistency achieved by the specificity of an affordability approach are outweighed by the constraints placed on the Director's ability to exercise best professional judgment on a case-by-case basis. EPA believes that this is a significant disadvantage of the affordability approach and welcomes comments on the use of specific affordability criteria.

A second issue which led EPA to propose the approach outlined in the proposed Guidance rather than an affordability approach involved the States' perceptions of the level of financial and economic analysis that it required. The Technical Work Group and Steering Committee representatives frequently voiced concerns that the financial and economic analysis required exceeded the scope of their normal regulatory functions (which generally focus on Clean Water Act programs). This potentially resource intensive analysis could place considerable strain on already limited resources. EPA acknowledges this problem and believes that the proposed approach provides a workable solution. However, EPA requests comments on the experience other regulatory agencies may have had in the application of affordability measures and how they might be most effectively and efficiently utilized.

EPA also seeks comment on the potential use of a strict benefit/cost analysis for making antidegradation decisions. Such an analysis would not include a mandatory expenditure on pollution prevention measures. In the proposed approach in the proposed Guidance, regulatory agencies already have to determine the economic and social benefits of the new or expanded activity. They must then compare these benefits with the economic and social

costs of water quality degradation. Social costs and benefits include the externalities associated with a private transaction. Social costs include such factors as loss of aesthetics, the destruction of habitats, the loss of a cold water source of a game fish, and increased risks to human health. Social benefits include a community's increased tax base that allows it to construct new parks, rehabilitate slums, and build recreation facilities.

In contrast to the proposed approach, under a strict benefit/cost analysis approach, decisions would rely entirely on economic efficiency criteria. They would not consider the financial condition of the entity. For such an approach, the proposed Guidance would have included a method for determining and listing social benefits and social costs. The proposed Guidance would have also distinguished between economic benefits and transfer payments. A strict benefit/cost analysis does not include the latter.

EPA did not propose a strict benefit/cost analysis approach because it is concerned that the approach would fail to take into consideration whether a significant lowering of water quality is necessary. As discussed above under "Background/Rationale", the determination that a significant lowering of water quality is necessary is one of the two mandatory demonstrations under the existing federal antidegradation policy. EPA does not believe that there is any compelling reason under the GLWQA or the CPA to deviate from this requirement of existing Federal guidance. EPA considered the use of cost/benefit analyses in a previous water quality standards rulemaking and, in part based on public comment, did not include such analyses in the final rule. The reader is referred to the preamble discussion in the November 8, 1983, Federal Register notice (49 FR 51400) for a more detailed discussion. Nonetheless, EPA requests comments on the appropriateness of a cost/benefit test in antidegradation decision-making.

b. *Economic Recovery.* Concerns were expressed during deliberations on the proposed Guidance that it is not sufficiently sensitive to firms that have been forced to reduce production as a result of an economic downturn or recession, and later want to increase production to previous levels. In particular, the Great Lakes region has been adversely affected in recent years, with major declines in production in industrial sectors such as iron and steel and automobiles and associated supporting industries.

The proposed Guidance tries to strike a balance between the need to protect and maintain high quality water and the need to accommodate growth, or in this case promote economic recovery. The proposed Guidance provides the regulatory agency with some flexibility that could be brought into the antidegradation decision involving a recovering firm. For example, in the establishment of the EEQ baseline estimate, the proposed Guidance provides the regulatory agency flexibility to account for recent economic downturns. Section D.2 of this preamble discusses using information from the preceding permit term that are representative of typical operations to determine the effluent quality. In general, all effluent quality data collected over the previous control document term (e.g., past five years) that are representative of the typical operation of the pollutant source should be utilized. However, the regulatory agency could account for any recent downturn in production by setting the effluent quality baseline to reflect conditions prior to the downturn, if information was available to suggest that it was likely to be temporary. Similar flexibility is provided the regulatory agency in the establishment of permit limits that are based on production levels. In addition, in the evaluation of social and economic importance, the regulatory agency could provide special consideration for the recovering firm.

EPA requests comment on whether the flexibility inherent in the proposed Guidance is sufficient to make it sensitive to the unique situation and needs of the recovering firm. EPA is also interested in comments on whether the proposed Guidance should make special provisions for recovering firms and what form the provisions should take.

c. *Best Available Technology.* Another issue that was raised regarding the Antidegradation Demonstration involves the case-by-case analysis of available pollution control alternatives and development of EEQ restrictions. Specifically, concerns were expressed that, with the EEQ, pollution prevention, and alternative or enhanced treatment analysis requirements, EPA was using antidegradation to require case-by-case development of best available technology conditions in NPDES permits, in lieu of the promulgation and subsequent re-evaluation of industry-wide guidelines pursuant to section 304 of the Clean Water Act.

EPA has developed effluent guidelines for 34 primary industrial point source discharger categories and numerous other secondary industrial discharger categories. Such guidelines identify the effluent limitations (technology-based effluent limitations) that shall be established in NPDES permits issued to point source dischargers in covered industrial categories to ensure that such dischargers satisfy the minimum pollution control technology requirements of the Clean Water Act. Among the minimum pollution control technology categories identified in the Clean Water Act are best practicable control technology currently available, best available technology economically achievable, best conventional pollutant control technology, and new source performance standards.

EPA believes the concerns expressed above are misplaced. The evaluation of control alternatives and EEQ would be required regardless of the quality of the effluent guidelines upon which the permits were based.

Antidegradation standards are a component of water quality standards. EPA and States routinely develop effluent limitations that are more stringent than technology-based limitations when necessary to protect water quality standards (water quality-based effluent limitations). Specifically, the Clean Water Act requires limitations as necessary to meet state water quality standards and EPA has developed a sizeable body of regulation and guidance to implement this requirement (e.g., 40 CFR 122.44(d) and the "Technical Support Document for Water Quality-based Toxics Control"). It is common practice in water quality-based permitting to require effluent limitations that are more stringent than National technology-based limitations as necessary to reflect site-specific conditions. EPA believes that antidegradation-based EEQ or alternative pollution prevention/control technology requirements fall within this context. Antidegradation requirements such as those proposed for this proposed Guidance to protect and maintain water quality would be necessary regardless of how stringent the National effluent guidelines were made. EPA welcomes comment on this issue.

d. *Mandatory Expenditures for Alternative or Enhanced Treatment Techniques.* As discussed above in detail, the proposed Guidance establishes the requirement that alternative or enhanced treatment techniques be implemented when such techniques prevent the need to significantly lower water quality and are available within a specified cost range. This provision reflects the priority of

the Great Lakes States to create a mandatory expenditure policy to protect and maintain water quality. Previous discussion in this preamble addressed the situation in which an entity can afford more than the additional 10 percent for pollution control and treatment to prevent the significant lowering of water quality. As that discussion indicated, the Antidegradation Decision guidance provides the Director ample latitude to require such additional expenditures, at his or her discretion, to prevent or reduce the significant lowering of water quality.

The proposed Guidance, however, provides no such latitude to the Director to circumvent the mandatory expenditure requirements when the results of the analysis required under section III.B of appendix E of the proposed Guidance show that alternative or enhanced treatment exists that is available within the defined cost range and prevents the significant lowering of water quality. The Antidegradation Decision guidance does not provide the Director with the ability to determine, on a case-by-case basis, that the amount defined as the mandatory expenditure is not affordable and, therefore, should be waived. During GLWQI Work Group deliberations, in considering this position for proposal, the Steering Committee recognized that there may be occasions when this requirement prevents entities from undertaking certain actions, which, as proposed, would significantly lower water quality, because they cannot afford the mandatory expenditure for treatment that would prevent the significant lowering of water quality. In the judgment of the Steering Committee, this concern is more than offset by the benefits of establishing a minimum expenditure policy to protect and maintain the quality of the Great Lakes System. EPA agrees with this position.

EPA invites comment on the policy position established by the proposed mandatory expenditure requirements. EPA also requests comments on the following alternative considerations regarding mandatory expenditures. EPA solicits comment on whether it is appropriate to require the mandatory expenditures set forth in section III.B of appendix E only when the expenditure prevents the significant lowering of water quality, or if it would be appropriate for such an expenditure to be mandatory if it reduced the extent to which water quality was significantly lowered. In the case of the latter, EPA also solicits comments on the extent to which the expenditure must reduce the significant lowering of water quality before it becomes a mandatory expenditure. Finally, EPA seeks comment on whether specific guidance should be included to assist the Director in making case-by-case decisions regarding expenditures greater than the proposed mandatory amount.

e. *Antidegradation Decision Presumption Against the Significant Lowering of Water Quality.* Sections IV.A.5 and IV.B.2 of appendix E of the proposed Great Lakes antidegradation guidance create an opportunity for the Director to defer the analysis of the social or economic developments and environmental effects associated with an action that significantly lowers water quality until after opportunity for public comment. Section IV.B.2 of appendix E of the proposed Guidance provides that:

> If the Director chooses to defer the review as provided in section IV.A.5 of this appendix, then the Director shall tentatively determine that the significant lowering of water quality is not allowable. The public notice shall state that the decision, based on a review of the social or economic developments and environmental effects associated with the action has been deferred, pending review of the comments received from the public, and that the tentative decision may subsequently be revised.

This provision reflects a presumption against the significant lowering of water quality which is consistent with the tone of the proposed Guidance as a whole. It is viewed as particularly important at the stage of the decision procedure when the public is asked to comment on the merits of a proposed action that would significantly lower water quality. During deliberations at Technical Work Group meetings and Steering Committee meetings to develop this proposed Guidance, several of the State representatives expressed concern that they needed the input of the public before they could do a meaningful assessment of the importance of the social or economic developments associated with a proposed action that would significantly lower water quality. However, in order to receive such input, within the public participation processes established for many of the existing regulatory programs, it would be necessary to propose a tentative decision regarding approval or disapproval of the request to significantly lower water quality to put out for public comment. The Steering Committee and EPA agreed that it was appropriate for the tentative decision put forth for public comment to be a denial, since, at that point there would be insufficient public input to ascertain that the social or economic development resulting from the proposed significant lowering of water quality would be important. To create a new public comment step outside of the existing procedures was an option, but it was considered too burdensome to the regulatory agencies to be feasible and a significant hinderance to timely decision-making.

Again, this provision represents the choice of the Steering Committee, with which EPA agrees, to presume that water quality be maintained and protected unless the public believes that the social or economic development that necessitates its significant lowering is important enough to support. EPA welcomes comments on this provision in the proposal, and on the position established by it.

G. Special Antidegradation Provisions for Lake Superior

1. Background

As stated earlier in this preamble discussion, in September 1991, the States of Michigan, Minnesota, and Wisconsin, the Province of Ontario, the government of Canada, and EPA entered into an agreement entitled "A Bi-National Program to Restore and Protect the Lake Superior Basin." This agreement established a "Lake Superior Zero Discharge Demonstration Program" with the stated goal being "To achieve zero discharge and zero emission of certain designated persistent, bioaccumulative toxic substances, which may degrade the ecosystem of the Lake Superior basin." The agreement identified three areas in which the parties agreed to undertake actions to pursue realization of this goal, one of which, "Special Protection Designations", is significant to this proposal. Under the Special Protection Designation heading, the Governors of the three Great Lakes States of Michigan, Minnesota, and Wisconsin ("Lake Superior States") commit to initiate appropriate State procedures to designate all waters of the Lake Superior Basin as Outstanding International Resource Waters (OIRWs) and certain special areas of the Lake Superior Basin as Outstanding National Resource Waters. The agreement further defines the intent and effect of such designations:

Under the OIRW designation, the increased discharge of certain designated persistent, bioaccumulative toxic substances will not be allowed without an adequate antidegradation demonstration which includes the installation of the best technology in process and treatment.

The purpose of this Lake Superior Basin—Outstanding National Resource

Water designation is to prohibit the new or increased discharges of certain designated persistent, bioaccumulative toxic substances by point sources in these areas, including respective buffer zones and transition areas as defined by the States.

The agreement requires that procedures to implement each designation be incorporated into the Great Lakes Water Quality Initiative Antidegradation Guidance.

2. Effect

This proposed Guidance contains several provisions, developed by the Lake Superior States and enumerated below, to implement the above conditions in the agreement. These provisions operate as additional restrictions, beyond the minimum requirements of the National antidegradation regulation, as this proposed Guidance has adapted it to apply to the entire Great Lakes System. Consequently, this notice puts these special Lake Superior provisions forward as State proposals, which EPA considers acceptable pursuant to section 510 of the Clean Water Act. The special provisions of this proposed Guidance included to implement the Lake Superior Special Protection Designations are as follows:

Appendix E, section II.A. Definition of Lake Superior bioaccumulative substances of immediate concern;

Appendix E, section II.A. Definition of Lake Superior Basin—Outstanding National Resource Waters;

Appendix E, section II.E.1 and E.2. Implementation procedures, entitled "Special Provisions for Lake Superior" that identify the effect of Lake Superior Special Protection Designations;

Appendix E, section III. Antidegradation Demonstration text reiterating the actions within the Lake Superior Basin, if designated an OIRW, that would necessitate a special demonstration by the entity proposing the action;

Appendix E, section III.C. Description of the special demonstration that must be provided by an entity proposing a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern to the Lake Superior Basin, if designated an OIRW;

Appendix E, section IV.A.3. Antidegradation Decision provision to ensure that the Director requires installation and utilization of best technology in process and treatment by entities that lower water quality as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern into the Lake Superior Basin, if designated an OIRW.

EPA notes that the Lake Superior special provisions in the antidegradation guidance are operative only when States designate waters of the Lake Superior basin as either Lake Superior Basin - Outstanding National Resource Waters or OIRWs. The proposed Guidance does not direct or require the Lake Superior States to make such designations.

Several of the above provisions require additional discussion to differentiate them from conditions more broadly applicable to the Great Lakes System and to describe how the special provisions operate within the larger antidegradation framework.

a. *Relationship to Other Antidegradation Requirements.* As indicated above, the special provisions applicable to designated portions of the Lake Superior Basin operate in addition to the antidegradation provisions otherwise applicable. Section II.E of appendix E of the proposed Guidance explicitly states this relationship.

i. *Example.* Upon designation of the Lake Superior Basin as an OIRW by the Lake Superior States a proposal by a point source to increase the discharge rate of mass loading of BCCs, which also includes certain Lake Superior bioaccumulative substances of immediate concern (BSICs), into an area of the basin that is a high quality water with respect to the pollutants in question would be covered as follows.

The proposal would necessitate an antidegradation demonstration, because it involves an increase in the rate of mass loading of BCCs (pursuant to section II.D.1 of appendix E) and an increased discharge of BSICs from a point source (pursuant to section II.E.2 of appendix E).

The demonstration would evaluate, pursuant to section III.A of appendix E of the proposed Guidance, pollution prevention alternatives available for all the pollutants, BCCs and BSICs. If prudent and feasible pollution prevention alternatives prevent the significant lowering of water quality (or increased discharge in the case of the BSICs), then the entity would not be required to provide any additional antidegradation demonstration information, because the significant lowering of water quality would not be allowable.

The second step of the demonstration differs between the BCCs and the BSICs. For BCCs not on the list of BSICs, the demonstration would evaluate alternative or enhanced treatment techniques available to prevent the significant lowering of water quality and identify the associated costs as specified in section III.B of appendix E of the proposed Guidance. If the costs were within the range defined by section III.B of appendix E of the proposed Guidance, no further antidegradation demonstration information would be required of the entity regarding the BCCs, because the significant lowering of water quality would not be allowable. For the BSICs, the demonstration would identify and evaluate the effectiveness of the best technology in process and treatment. The proposed Guidance leaves the determination of what constitutes best technology in process and treatment to the individual Lake Superior States, with the understanding that it will always be at least as stringent as the alternative or enhanced treatment identified for pollutants other than BSICs, that the cost of the technologies is not a factor in the decision, and that in general the requirement is intended to force implementation of "state of the art" pollution controls.

In the third step, where the application of alternative or enhanced treatment techniques available within the mandatory cost range does not prevent the significant lowering of water quality by BCCs or the implementation of best technology in process and treatment does not prevent the increased discharge of BSICs, the entity must provide the important social or economic development demonstration required by section III.D of appendix E of the proposed Guidance. This information is evaluated in the same manner for all pollutants.

Finally, section IV.A.1 of appendix E of the Antidegradation Decision instructs the Director to require the implementation of prudent and feasible pollution prevention alternatives for both types of pollutants. The information developed in the second step is handled in separate provisions in the Antidegradation Decision part of the proposed Guidance. For the BCCs, section IV.A.2 of appendix E of the proposed Guidance provides that the Director must deny the request to significantly lower water quality if alternative or enhanced treatment technologies exist, the cost of such treatment falls within a defined range and its implementation prevents the significant lowering of water quality. For the BSICs, section IV.A.3 of appendix E of the proposed Guidance provides that the Director must require the installation and utilization of the best technology in process and treatment and establish limitations on the BSICs accordingly. In section IV.A.4 of appendix E of the proposed Guidance, actions that are not prevented

from significantly lowering water quality (or increasing the discharge of BSICs) by the decisions in section IV.A.1 through A.3 of appendix E of the proposed Guidance are evaluated in light of the associated social or economic developments and environmental effects and a decision proposed regarding the extent to which water quality may be significantly lowered (or the discharge of BSICs increased). Both actions involving BCCs and BSICs are subject to this evaluation. As discussed in detail elsewhere in this preamble, as a result of this evaluation the Director may require other controls on BCCs on a case-by-case basis provided they are no less stringent than the controls required under section IV.A.2 of appendix E of the proposed Guidance.

b. *Lake Superior Basin—Outstanding National Resource Waters.* The special provisions created for Lake Superior define a potential new State designation, that of Lake Superior Basin—Outstanding National Resource Water, and specify the effect of such a designation (see sections II.A and II.E.1 of appendix E of the proposed Guidance, respectively). EPA wants to clarify that this new designation created for Lake Superior is different than the Outstanding National Resource Water designation defined in section II.A of appendix E of the proposed Guidance. The terminology for the Lake Superior designation was chosen by the Lake Superior States to conform as closely as possible to the language in the agreement, while still being distinguishable from the ONRW designation defined in the National antidegradation regulation and used in this proposed Guidance. EPA also notes that the creation of the new Lake Superior Basin—Outstanding National Resource Water designation does not affect the ability of a State to designate a portion of the Lake Superior Basin as an ONRW (as defined in section II.A. of appendix E of the proposed Guidance) and that such a designation would have the effect specified in section II.C of appendix E of the proposed Guidance.

c. *Lake Superior Bioaccumulative Substances of Immediate Concern.* Section II.A of appendix E of the antidegradation guidance identifies the substances that are subject to the special Lake Superior provisions of the proposed Guidance. These substances were identified in the agreement and are proposed by the Lake Superior States for this proposed Guidance, because they are the persistent, bioaccumulative toxic pollutants considered to pose the most significant risk to the Lake Superior Basin. The proposed Guidance provides that additional substances may be added by a State in the future, after the opportunity for public review and comment. EPA wants to clarify that designation as a Lake Superior bioaccumulative substance of immediate concern has no effect on the status of such pollutants in Lake Superior Basin waters not designated as Lake Superior Basin—Outstanding National Resource Waters or OIRWs or in other waters of the Great Lakes System.

EPA invites comment on all aspects of the special provisions for Lake Superior.

H. Offsets

During Technical Work Group deliberations on the GLWQI, an approach was evaluated that would have required, as a part of the antidegradation review, consideration of controls on unregulated pollutant sources to offset proposed increased discharges from a regulated source. The approach was referred to as "offsets", and it was intended to provide the Director with an additional mechanism to prevent significant lowering of water quality.

The offset approach would have required that an entity seeking to significantly lower water quality with respect to any pollutant, identify other sources, currently not subject to regulation, of that pollutant to the water body in question. The entity would be required to determine if any such sources were amenable to control such that the reduction in the loading from the unregulated source would offset the proposed increase in loading from the entity. If the opportunity for such offsets was found and incorporated as an enforceable requirement of the entity's control document (e.g., NPDES permit) the entity could avoid the additional antidegradation demonstration requirements in the Great Lakes Antidegradation Guidance. That is, the Director could in such a case determine that water quality was not significantly lowered. One variation to the general offset approach considered by the GLWQI Technical Work Group is highlighted for comment. The Technical Work Group considered requiring that additional removals of BCCs be mandated under the offset provision in order for an action to be relieved of further antidegradation demonstration requirements. That is, the entity seeking to increase its mass loading rate of a BCC would have been required to find and control unregulated, uncontrolled sources of that BCC in an amount greater than the proposed increase, in order for the increase to be considered offset. Several alternative factors were considered, ranging up to 1.5, which would have mandated 1.5 times the amount of the proposed increased rate of pollutant loading be removed from currently unregulated, uncontrolled sources to achieve an offset.

EPA is not proposing any offset provision in the Great Lakes Antidegradation Policy in the **Federal Register** notice. In the GLWQI deliberations, EPA and the Great Lakes States shared concerns that implementation of the offset concept is not yet technically feasible or legally enforceable. That is, although conceptually possible, it was expected to be too difficult to quantitatively implement and enforce the concept of offsets. In particular, the likelihood that controls on currently unregulated, uncontrolled sources could be an enforceable requirement of a permit was strongly questioned and anticipated to result in excessive administrative burdens. In addition, the likelihood that an entity seeking an increased discharge could identify and control an unregulated source of contamination was questioned by many Work Group members.

Although the offset concept is not being proposed in the Great Lakes Antidegradation Policy, other parts of the Great Lakes Water Quality Guidance may allow "trading" of pollutant load allocations between pollutant sources, both point and nonpoint. In particular the reader is referred to the discussion of TMDLs in the implementation procedures (see section VIII.C of this preamble). However, any such reallocation of pollutant loads to pollutant sources might subject them to the requirements of this Antidegradation Policy.

EPA requests comment on the offset approach considered for the Great Lakes Antidegradation Policy. EPA also solicits comment on any information that regulatory agencies may have on actual experience using an offset approach to control pollution sources.

I. Incorporation Into State Water Quality Standards.

The Great Lakes Critical Programs Act requires the Great Lakes States to adopt antidegradation policies for the Great Lakes System that are consistent with the final Great Lakes Guidance published by EPA. The **Federal Register** notice proposes such Guidance. When evaluating whether or not the States adopt antidegradation policies that are consistent with the final Great Lakes Water Quality Initiative Antidegradation Policy, EPA will follow the provisions of 40 CFR 132.6, proposed in the proposed Guidance.

EPA expects that upon finalization of the proposed Guidance, the States will adopt into their water quality standards regulations language identical to or no less restrictive than the language set forth in the Great Lakes Water Quality Initiative Antidegradation Policy (appendix E to part 132). Specifically, the States must adopt into their water quality standards regulations the Antidegradation Standard, Antidegradation Implementation Procedures, Antidegradation Demonstration, and Antidegradation Decision provisions of the final Guidance. EPA believes that these provisions collectively represent the Antidegradation Policy required by the Great Lakes Critical Programs Act. The State regulations need not reproduce, verbatim, the Great Lakes Guidance. However, the antidegradation policy adopted into State regulation must result in equal protection and maintenance of water quality as would this proposed Guidance in the same situation.

As indicated in proposed 40 CFR 132.4(a)(6), the Great Lakes States are not required to adopt the provisions of the Antidegradation Policy that provide special protection to Lake Superior. These provisions are enumerated in 40 CFR 132.4(a)(6) and discussed in this preamble (see section VII.G.2.). EPA is including these provisions in the Antidegradation Policy to provide guidance to the Great Lakes States signatory to the "Bi-National Program to Restore and Protect the Lake Superior Basin." EPA does not intend to promulgate the Lake Superior special provision of the Antidegradation Policy pursuant to proposed 40 CFR 132.5(d) if a Great Lakes State fails to do so.

At several points in this preamble, various alternatives are identified to accomplish specific requirements set forth in the proposed Guidance (e.g., options for EEQ controls). A State is free to implement the requirement using the identified alternatives or others that may be equally effective. Finally, there are a number of decisions required by the proposed Guidance which allow the State to exercise flexibility in response to situation-specific conditions (e.g., the determination of what constitutes "prudent and feasible" pollution prevention alternatives). As noted in the preamble, EPA is requesting comment on whether the proposed Guidance provides adequate direction to the States for making such decisions.

A State may adopt an antidegradation policy for the Great Lakes System, which is more stringent than that specified in the proposed Guidance. Finally, to the extent that a State can demonstrate that its current water quality standards regulations or statutes contain some of all of the proposed Guidance being proposed here for the Great Lakes System, the State need not reproduce that portion of the proposed Guidance as separate Great Lakes standards.

VIII. General Implementation Procedures

A. Site-Specific Modifications to Criteria

National guidance provided in the "Water Quality Standards Handbook" (1983) (the Handbook) indicates that States may modify generally applicable State criteria and set site-specific water quality criteria for the protection of aquatic life when: the local water quality parameters such as pH, hardness, temperature, color, etc., alter the biological availability and/or toxicity of a pollutant; and/or the sensitivity of the local aquatic organisms (i.e., those that would live in the water absent human-induced pollution) differs significantly from the species actually tested in developing the criteria. This Handbook is available in the administrative record for this rulemaking. Copies are also available upon written request to the address listed in section XIII of this preamble. State-wide water quality criteria for aquatic life may be unnecessarily stringent or underprotective in a given water body if the physical and chemical characteristics of the water body ameliorate or enhance the biological availability and/or toxicity of a given chemical. In addition, species capable of living at a particular site, if there were no human-induced pollution, may be more or less sensitive than those species represented in the development of the State-wide criteria. Developing site-specific criteria for aquatic life is a way of taking unique conditions of a specific portion of a water body into account so that criteria adequately protect aquatic life from acute and chronic effects. Chapter 4 of the Handbook provides procedures for setting site-specific criteria for aquatic life which may be utilized as a basis for establishing water quality standards. Using those procedures, the resulting chronic or acute aquatic life criteria may be more or less stringent than the otherwise applicable State criteria.

There is presently no such specific guidance regarding site-specific modifications to human health water quality criteria. Additionally, there is presently no National guidance for deriving wildlife water quality criteria or site-specific modifications to wildlife criteria. However, present regulations do allow States to modify any criteria to reflect site-specific conditions provided that the modified criteria are protective of designated uses and based on sound scientific rationale (40 CFR 131.11). One of the issues that States might consider in developing site-specific modifications to human health criteria, for example, is local fish consumption rates. (See, generally, memorandum from LaJuana S. Wilcher to Regional Water Management Division Directors, dated January 5, 1990, which is available in the administrative record for this rulemaking.)

National water quality criteria are based upon data from, and assumptions specifically applicable to, the entire United States. The Great Lakes criteria/values proposed in the proposed Guidance differ from the National criteria in part because they were derived using data and assumptions relevant to the Great Lakes System. For example, certain aquatic life criteria/values have been lowered to protect commercially or recreationally important species within the Great Lakes System (e.g., steelhead rainbow trout). As another example, BAFs used in developing human health criteria/values for the Great Lakes System assume a fish lipid content of five percent based on Great Lakes-specific data instead of the National average lipid content of three percent used for the derivation of National criteria. The purpose of using Great Lakes-specific data and assumptions in deriving criteria/values is to more accurately calculate ambient criteria levels that are protective of aquatic life, wildlife and humans within the Great Lakes System.

Even though the Great Lakes criteria/values already reflect Great Lakes-based modifications of the National criteria, there may be local areas within the Great Lakes System where conditions vary sufficiently from the assumptions underlying the methodologies for deriving Tier I criteria and Tier II values to merit the application of more narrowly applicable site-specific criteria. Procedure 1 of the proposed Implementation Procedures specifies the circumstances where a State may develop site-specific modifications to the Great Lakes aquatic life, human health and wildlife criteria as well as bioaccumulation factors. The proposed Implementation Procedures allow modifications to be made to acute or chronic aquatic life criteria/values in a manner consistent with Chapter 4 of the Handbook. This Handbook only covers site-specific water quality criteria for the protection of aquatic life. Consistent with that guidance, site-specific modifications to acute and chronic

aquatic life criteria/values for the Great Lakes System under the proposed Guidance may result in more or less stringent aquatic life criteria/values than those calculated using the Great Lakes aquatic life methodology.

The Handbook only sets forth procedures for developing site-specific modifications to aquatic life criteria when such modifications are appropriate because either local water quality parameters alter the biological availability or toxicity of a pollutant, or the sensitivity of local aquatic organisms differ significantly from the species actually tested in developing criteria. Proposed implementation procedure 1, however, goes beyond the Handbook by also allowing the Great Lakes States and Tribes to develop site-specific modifications to chronic aquatic life criteria/values for the Great Lakes System to reflect local physical and hydrologic conditions. Specifically, the Great Lakes States and Tribes would be allowed to also develop site-specific modifications to chronic aquatic life criteria/values by showing that either hydrologic conditions or physical conditions related to the natural features of a water body, such as lack of a proper substrate, cover, flow, depth, pools, riffles, and the like, unrelated to ambient water quality, preclude aquatic life from remaining in the site for 96 hours or more. These site-specific conditions may also be taken into account in determining whether a discharge must comply with the chronic whole effluent toxicity requirements specified in proposed procedure 6.A.2. This provision is discussed in section VIII.F of the preamble.

As explained above in the section of this preamble on the Applicability of the Tier I and Tier II Criteria/Values, the Initiative Steering Committee intended that the States be given additional flexibility to modify chronic aquatic life criteria/values where physical and hydrologic conditions prevent aquatic life from remaining in a specific water body for 96 hours or more. The Steering Committee was concerned that the chronic aquatic life criteria/values would be unnecessarily stringent in protecting aquatic life in such locations because the chronic aquatic life methodologies assume that aquatic life are exposed to pollutants in a specific water body for at least 96 hours. Consistent with the Steering Committee deliberations, the proposed Guidance allows the States to develop site-specific modifications to the chronic aquatic life criteria/values to reflect local physical and hydrologic conditions.

EPA believes that it is possible that there may be sites within the Great Lakes System where aquatic life will not remain at the site for more than 96 hours. Consequently, aquatic life can be protected from suffering chronic health effects at such sites by criteria/values less stringent than those developed under the proposed Great Lakes Guidance. Similarly, in sites where conditions preclude all but a few forms of aquatic life from living in a specific site, it is possible that the few forms of aquatic life living at the site may be protected by less stringent criteria/values. Because the physical and hydrologic condition justification for the exception to procedure 6.A.2 of appendix F is functionally equivalent to a justification for the removal of a designated use at 40 CFR 131.10(g)(2), (4) and (5), EPA expects this exception will typically be used for waters where a full aquatic life use is unattainable. States must ensure that the application of this exception does not impair the water quality of downstream waters.

The proposed Great Lakes Guidance does not provide for the same flexibility in terms of site-specific modifications to the wildlife and human health criteria/values or to bioaccumulation factors as is available for aquatic life criteria/values. The proposed Guidance restricts site-specific modifications to human health criteria/values, wildlife criteria/values, or bioaccumulation factors to only those which would increase the level of protection for humans and wildlife. The proposed Guidance, in allowing States to adopt less stringent criteria/values for aquatic life, but not for human health and wildlife, is consistent with the Steering Committee's proposal.

EPA believes that although less stringent site-specific criteria/value modifications can be justified for aquatic life, similar justifications may not exist with respect to less stringent wildlife and human health criteria/values or BAFs. For example, EPA does not believe that there are natural conditions in the Great Lakes System which preclude humans and wildlife from consuming fish and recreating in specific sites. Similarly, even if there may be local populations of humans and wildlife less exposed to toxicants than assumed in deriving the State-wide criteria, a less stringent site-specific modification may not be appropriate given the mobility of humans and wildlife into and out of these localized areas. Instead, EPA assumes that, due to their mobility, humans and wildlife feed from and recreate in all portions of the Great Lakes System. EPA believes that these assumptions are reasonable and appropriate in light of the goals and objectives of the Clean Water Act and the Great Lakes Water Quality Agreement. However, EPA requests comment on these assumptions.

The proposed Guidance allows Great Lakes States and Tribes to adopt site-specific modifications allowing for application of less stringent aquatic life criteria/values where local water quality parameters alter the biological availability and/or toxicity of a pollutant, but does not allow similar site-specific modifications for human health and wildlife criteria/values. This proposal is consistent with the proposal of the Steering Committee. In those cases where the biological availability and/or toxicity of a pollutant is decreased by local water quality conditions (e.g., pH, hardness, alkalinity, suspended solids), a less stringent criteria/value for aquatic life will adequately protect aquatic organisms. The proposed Guidance reflects a more conservative approach with respect to humans and wildlife by allowing only more stringent site-specific modifications. EPA believes that this conservative approach is appropriate because of the mobility of humans and wildlife and their potential for exposure to these pollutants in different areas of the Great Lakes basin. In addition, there is not adequate information to quantify the total environmental uptake by humans and wildlife from different exposure routes. In light of these uncertainties, EPA proposes to use an approach that may result in human health and wildlife criteria/values which are somewhat overprotective in those cases where local water quality parameters decrease the biological availability and/or toxicity of a water body. This approach would err on the side of being overprotective rather than underprotective. EPA invites comment on whether the proposed approach for humans and wildlife is reasonable or whether less stringent site-specific modifications should be allowed under certain circumstances.

Specifically, EPA requests comment on whether the proposed Guidance should be modified to allow for development of less stringent site-specific modifications to all types of criteria/values (including human health and wildlife) and BAFs under any of the scenarios described below or under any other scenarios. Comment is requested on whether less stringent site-specific modifications should be allowed for human health and wildlife criteria/values where local water quality parameters decrease the biological availability and/or toxicity of a pollutant. EPA invites specific comment on adding to the human health and

wildlife provisions the same text as appears in section A.1.a of procedure 1 of appendix F for aquatic life. EPA also invites comment on whether less stringent site-specific modifications should be allowed for bioaccumulative pollutants where local physical or hydrologic conditions do not allow aquatic life that may be consumed by humans or wildlife to be present in the water body long enough to reach steady-state bioaccumulation. EPA further invites comment on whether less stringent site-specific modifications should be allowed for bioaccumulation factors if reliable data shows that local bioaccumulation is lower than the system-wide value.

EPA also invites comment on whether it should allow in the final Great Lakes Guidance the development of less stringent site-specific modifications to the aquatic life criteria/values, as proposed today. Eliminating the option would enhance consistency of criteria in the Great Lakes System.

The proposed Guidance for wildlife criteria/values states that modifications may be made on a site-specific basis to provide an additional level of protection for a species determined to require greater protection, for any reason. The proposed Guidance specifies that such site-specific modifications may be accomplished through the incorporation of an additional uncertainty factor in the equation for the wildlife value. The text presented below provides additional guidance on the equation for the calculation of the wildlife value and is in keeping with the intent of the Initiative Committees. EPA requests comment on the use of the following alternate text to replace the text of procedure 1.A.2 of appendix F of the proposed Guidance.

Wildlife criteria or values may be modified on a site-specific basis to provide an additional level of protection for a species determined to require greater protection, for any reason. This may be accomplished through the use of an additional uncertainty factor in the equation for the wildlife value as presented below:

$$WV = \frac{(NOAEL \times SSF \times ISF) \times Wt_A}{W_A + (F_A \times BAF)}$$

where:

The terms are defined in appendix D, section II of the proposed Guidance except that:

NOAEL=No Observed Adverse Effect Level in milligrams per kilogram body weight per day (mg/kg/d) determined for the taxonomic class to which the species requiring greater protection belongs.

Wt_A=Average weight in kilograms (kg) of the species requiring greater protection.

W_A=Average daily volume of water consumed by the species requiring greater protection, in liters per day.

F_A=Average daily amount of food consumed by the species requiring greater protection, in kilograms per day (kg/d).

BAF=Aquatic life bioaccumulation factor in liters per kilogram (L/kg) for the trophic level(s) at which the species requiring greater protection feeds. The BAF is chosen using guidelines for wildlife presented in appendix B, section V.B of the proposed Guidance.

ISF=Intraspecies sensitivity factor. An uncertainty factor to account for differences in toxicological sensitivity among members of the population of the species requiring greater protection (may be 0.1 or less).

The equation presented above for the calculation of a site-specific wildlife criterion for species requiring greater protection incorporates the use of the NOAEL determined for the taxonomic class to which the species requiring greater protection belongs. It is possible that the site-specific wildlife criterion may be based on a species from a different taxonomic class than the wildlife value used to derive the State-wide wildlife criterion. However, site-specific modifications may only be made when the site-specific wildlife criterion which results is more stringent than the State-wide wildlife criterion. In addition, the above equation for the wildlife value includes an intraspecies sensitivity factor (ISF) to provide additional protection to individuals in a population since the proposed wildlife methodology is derived to protect wildlife populations, not individuals within the population. Therefore, EPA highlights the use of site-specific modifications for the protection of individuals within a population for species requiring greater protection for public comment.

Section II.K of today's preamble states that EPA has initiated informal consultation with the FWS to ensure that the requirements in part 132 are not likely to cause jeopardy for threatened or endangered species in the Great Lakes System. EPA invites comments on whether procedure 1 in appendix F to part 132 should contain specific text requiring modification on a site-specific basis of aquatic life and wildlife criteria/values to provide protection appropriate for threatened or endangered species.

Individual Great Lakes States may make a decision to modify any aquatic life, human health or wildlife criterion/value consistent with the requirements of this guidance. Site-specific modifications to criteria must be submitted to EPA for approval or disapproval in accordance with section 303(c) of the Clean Water Act and 40 CFR 131.20. In addition, the proposed Guidance would require that the State share information concerning site-specific modifications to Great Lakes criteria/values with other Great Lakes States. The State must notify the other Great Lakes States at the time a State proposes any site-specific modification and supply a justification for any less stringent site-specific modification. The State may send a notice to the appropriate State agency designees and/or notify the EPA Region V Clearinghouse to comply with this requirement. The purpose of the notice is to allow other Great Lakes States to comment on proposed site-specific modifications to criteria/values since a primary objective of today's proposed Guidance is to provide consistency among the Great Lakes States.

EPA invites comment on two possible alternatives to the proposed procedure 1 of appendix F. Under the first alternative, site-specific modifications as provided in procedure 1 would be available only for tributaries and connecting channels, not the open waters of the Great Lakes. This first alternative was developed by the Technical Work Group, which felt that the Great Lakes criteria provide appropriate protection for the open waters of the Great Lakes and that the proposed procedure 1 should only be used for rather small localized areas to provide needed additional protection of specific subpopulations within those areas and, for aquatic life, limited less stringent modifications. The reason for the Work Group's proposal was to ensure that a consistent set of

requirements is applied throughout the open waters of the Great Lakes.

Although EPA recognizes that one of the goals expressed in the legislative history of the Great Lakes Critical Programs Act of 1990 is to promote consistency in Great Lakes water quality standards, EPA does not view this goal as overriding the authority specifically reserved to States and Tribes in section 510 of the Clean Water Act to enact more stringent requirements than necessary to implement Clean Water Act requirements. Furthermore, Article IV(a) of the Great Lakes Water Quality Agreement also clearly provides that the Agreement is not intended to preclude adoption of more stringent requirements. Consequently, EPA is not authorized under the Clean Water Act to prohibit States from adopting more stringent criteria/values for the open waters of the Great Lakes System. For these reasons, EPA is not proposing this first alternative in today's proposed Guidance. Nevertheless, EPA invites comment on this first alternative, and on EPA's interpretation of the Clean Water Act.

A second alternative would provide that the site-specific modification procedures in procedure 1 of appendix F would differ for pollutants that are not bioaccumulative chemicals of concern (BCCs). For non-BCCs, this alternative approach would allow site-specific modifications for human health and wildlife criteria/values that are either more stringent or less stringent than the criteria/values derived using the proposed Guidance methodologies, depending on local considerations (e.g., water quality characteristics). This alternative approach would provide additional flexibility to the States in conducting site-specific modifications for non-BCCs.

This second alternative was not viewed favorably by the Great Lakes Steering Committee. EPA is proposing today that only those site-specific modifications which result in more stringent human health and wildlife criteria/values be allowed under the proposed Great Lakes Guidance, consistent with the Steering Committee proposal. However, EPA invites comment on this possible alternative approach.

B. Variances From Water Quality Standards for Point Sources

The proposed Water Quality Guidance for the Great Lakes System proposes Guidance to be followed by the Great Lakes States and Tribes in the development of procedures for granting variances from water quality standards for point sources at 40 CFR part 132, appendix F, procedure 2. This proposed Guidance is not intended to require the States or Tribes to include a variance provision as part of their standards program. Rather, EPA is proposing to permit Great Lakes States and Tribes to include water quality standards variance provisions in their water quality standards, and grant variances based on those provisions, as long as they are at least as stringent as those proposed herein. The proposed water quality standards variance procedure provides a mechanism for States and Tribes to maintain goal standards and assure compliance with sections 301(b)(1)(C) and 402(a)(1) of the CWA that require NPDES permits meet applicable water quality standards, while granting temporary relief to point source dischargers.

The intent of the variance provision is to: Provide a mechanism by which permits can be written to meet a modified standard where compliance with the underlying water quality standard is demonstrated to be infeasible; encourage maintenance of original standards as goals rather than removing uses; identify conditions under which such variances may be granted; identify the requirements for variance applications; and ensure the highest level of water quality achievable while the variance is in effect.

1. Current EPA Policy

For some time, EPA has acknowledged State or Tribal authority to grant variances from water quality standards and has approved both State-adopted variances procedures and State-issued individual variances. Because the Clean Water Act does not speak directly to water quality standards variances and EPA's regulations merely allow States to adopt variance provisions subject to EPA approval, the permissible scope of water quality standards variances must be discerned from the general structure of the Clean Water Act and by analogy. This process, conducted over the past 15 years, has resulted in a variety of guidance and interpretive documents which, together, set out the evolution of EPA's current policy on water quality standards variances.

EPA first formally indicated allowability of State water quality standards variance provisions in Decision of the General Counsel No. 44, dated June 22, 1976, which specifically considered an Illinois variance provision. EPA expanded upon the acceptability of State water quality standards variance procedures in Decision of the General Counsel No. 58 (44 FR 39508) dated March 29, 1977 (OGC #58):

> * * * Rather than downgrading the standard [note: downgrading the standard is currently referred to as removing a designated use in EPA's Water Quality Standards Regulation at 40 CFR 131.10(g)] for an entire stream, or stream segment, some States have maintained the standard, but provided that individual dischargers may receive variances for a limited time period from meeting standards. This approach appears to be preferable environmentally. The more stringent standard is maintained and is binding upon all other dischargers on the stream or stream segment. Even the discharger who is given a variance for one particular constituent * * * will be required to meet the applicable criteria for other constituents. The variance is given for a limited time period and the discharger must either meet the standard upon the expiration of this time period or must make a new demonstration of unattainability.
>
> EPA will accept such variance procedures as part of State water quality standards as long as they are consistent with the substantive requirements of 40 C.F.R. 130.17 [note: 40 CFR 130.17, as revised on November 8, 1983, is currently codified as Water Quality Standards at 40 CFR 131]. Therefore, variances can be granted by States only when achieving the standard is unattainable. In demonstrating that meeting the standard is unattainable, the State must demonstrate that treatment in excess of that required pursuant to section 301(b)(2) (A) and (B) of the CWA is necessary to meet the standard and also must demonstrate that requiring such treatment will result in substantial and widespread economic and social impact * * *.
>
> The justification submitted by the State should include documentation that treatment more advanced than that required by section 303(c)(2)(A) and (B) has been carefully considered and that alternative effluent control strategies have been evaluated.
>
> Since State variance proceedings involve revisions of water quality standards, they must be subjected to public notice, opportunity for comment, and public hearing. (See section 303(c)(1) and 40 C.F.R. 130.17(a).) The public notice should contain a clear description of the impact of the variance upon achieving water quality standards in the affected stream segment.

OGC #58 has formed the basis for EPA's water quality standards variance policy to the present. This decision is available in the administrative record for this rulemaking.

Subsequent guidance has elaborated on or clarified the policy over the years. For example, the Director of EPA's Criteria and Standards Division transmitted EPA's definition of a water quality standards variance to the Regional Water Quality Standard Coordinators on July 3, 1979 (1979 Guidance), which is available in the administrative record for this rulemaking, variances are granted for a specific period of time and must be rejustified upon expiration but at least every three years. The three-year

rejustification is derived from the triennial review requirements of section 303(c) of the CWA.

The 1983 revisions of the Water Quality Standards Regulation allowed States to include variances in State standards, subject to EPA review and approval (40 CFR 131.13). In the preamble discussion of the General Policies Section (1983 Preamble at 48 FR 51403), EPA re-affirmed the allowability of State water quality standards variances mirroring the requirements as set out in OGC #58:

> EPA has approved State-adopted variances in the past and will continue to do so if: each individual variance is included as part of the water quality standard * * * and is granted based on a demonstration that meeting the standard would cause widespread social and economic impact, the same test as if the State were changing a use based on widespread social and economic impact * * * With the variance provision, NPDES permits may be written such that reasonable progress is made toward attaining the standards without violating section 402(a)(1) of the CWA which states that NPDES permits must meet the applicable water quality standards.

The 1983 preamble noted that water quality standards variances were appropriate for granting relief to NPDES discharge permits and linked the granting of such variances to reasonable progress being made toward meeting the underlying standards.

In December 1983, EPA produced a Handbook to assist in implementing the 1983 Regulation. The Handbook explains that in showing widespread social and economic impact, the determining factor is whether the impact on the discharger is sufficient to have a substantial and widespread impact on the affected community and not just on the discharger.

On March 15, 1985, the Director of the Office of Water Regulations and Standards, responding to questions raised on water quality standards variances, issued a reinterpretation of the factors that could be considered when granting variances (1985 Guidance). This memorandum explained that variances could be based on any of the grounds outlined in 40 CFR 131.10(g) for removing a designated use, not merely on the widespread social and economic impact ground. This interpretation was based on the fact that, under section 510 of the Clean Water Act, States have the right to establish more stringent standards than those suggested by EPA. Therefore, as long as any temporary water quality standards variance conforms to the requirements established in 40 CFR 131.13(g) for removal of a designated use, it would be more stringent than the Federal requirements since it would be a temporary rather than permanent change.

2. GLWQI Proposal (40 CFR Part 132, Appendix F, Procedure 2)

The proposed Great Lakes Guidance, procedure 2 of appendix F of part 132, proposes a procedure to ensure consistent application of water quality standards variances for the Great Lakes States and Tribes. Variances can be requested for any of the grounds which justify removing designated uses set out at 40 CFR 131.10(g).

The six conditions set forth in proposed procedure 2.C.1 through 2.C.6 of appendix F are, as discussed above, taken from 40 CFR 131.10(g) and are generally self explanatory. EPA has not provided further details or definition for these six conditions for that reason and because it could interfere with the intention to give the States and Tribes some latitude in applying this provision on a case-by-case basis. However, EPA solicits comments on whether procedure 2.C.3 of appendix F should be clarified to prevent any bootstrapping by parties who have contributed to the human-caused conditions or sources of pollution. That is, should parties that have contributed to conditions that prevent water quality standards from being attained be explicitly prohibited from being granted a water quality standards variance based on that non-attainment? An example of such bootstrapping might be a discharger, whose past or present activities (including, but not limited to, discharges, spills, or leaching of pollutants) have contaminated sediments which currently cause non-attainment of water quality standards, requesting a water quality standards variance based on that previous and/or continuing, pollution.

As mentioned in the discussion on pollutants in intake waters (section VIII.E of the preamble), variances may be available under procedure 2.C.6 of appendix F for certain dischargers where the intake water contains a ubiquitous pollutant which is found in almost all water bodies in a watershed at about the same concentration due to watershed-wide contributions from nonpoint sources and where removing the pollutant would cause a substantial and widespread social and economic impact. In the case of small dischargers unable to meet the widespread social and economic impact test, a variance may be available under procedure 2.C.3 of appendix F, which applies where there are human caused conditions or sources of pollution that cannot be remedied, at least in the near term. In either case, the variance would establish an interim criterion for the pollutant that accounts for the background level and the level of incidental removal obtained by the discharger's proposed or existing treatment system. EPA seeks comment on whether such variances addressing ubiquitous pollutants should be available to new as well as existing dischargers. Comments are also solicited on whether this, or any of the other six conditions for granting a water quality standards variance, require further explanation or clarification.

The proposed Guidance would not require the Great Lakes States or Tribes to have a variance procedure for water quality standards, but if they adopt one, it would be required to be consistent with the procedure proposed herein. In the proposed Guidance, Great Lakes States and Tribes would retain the discretion to define what specific information they will require in a permittee's variance demonstration and application pursuant to procedures 2.C and 2.D of appendix F. Great Lakes States and Tribes would also have the discretion to define the decision criteria the Great Lakes State or Tribe will use when approving or disapproving a variance under procedure 2.F of appendix F, as long as they are at least as stringent as the requirements proposed in procedure 2.C, subject to EPA review and approval.

A Great Lakes State or Tribe choosing to adopt variance procedures will provide information, pursuant to part 132.5(b)(3) of the proposed Guidance, on the requirements for the variance demonstration and application as well as the evaluation criteria that the State or Tribe would use to approve or disapprove specific variances. This will assure that: the public has sufficient information to comment on the appropriateness of a State's or Tribe's WQS variance process pursuant to part 132.5(c) of the proposed Guidance; EPA has sufficient details to determine if the State or Tribe procedures comply with the CWA and are approvable pursuant to part 132.5(d) of the proposed Guidance; and both EPA and the public have adequate information on which to judge State or Tribal compliance with its own procedures when making individual variance decisions. EPA requests comment on whether the appropriate amount of latitude is given the States and Tribes and on whether it will provide for the consistency within and between State and Tribal programs in the Great Lakes System that the proposed Guidance is intended to provide. Neither the procedure proposed, nor any State or Tribal procedures adopted consistent with it,

would require States or Tribes to grant variances in any specific circumstance.

EPA requests comment on whether this section provides adequate guidance, and sufficient detail, for the Great Lakes States and Tribes to make appropriate decisions on water quality standards variance applications.

3. Applicability

The Guidance requires variances apply only to the permittee requesting the variance and only to the pollutant(s) specified. The water quality standards for the affected water body are not otherwise changed by a water quality standards variance. Although a variance modifies specific criteria for specific NPDES discharges, the underlying water quality standards for the water body have full force and effect for all other purposes, and any controls placed on other sources of pollution to the water body should be designed to meet those standards. Any TMDL/WLA/LA, NPDES permit (other than the specific one modified pursuant to the variance), or other water pollution control requirement is to be implemented in a manner consistent with the appropriate implementation absent the variance.

The proposed Guidance would not allow variances for new or recommencing dischargers as those terms are defined at 40 CFR 122.2. Water quality standards variances are intended to provide relief, where appropriate, to existing dischargers. Variances could apply to existing dischargers even where water quality standards have been on the books for a while (as long as they have consistently not been attained). New and recommencing dischargers should design their facilities and treatment to meet water quality standards. EPA requests comment on the appropriateness of these restrictions and on whether variance requirements for increasing dischargers should be different from those for existing dischargers as those terms are defined at procedure 9.D of appendix F of the proposed Guidance and whether the definition for new discharge at procedure 9.D of appendix F of the proposed Guidance is more appropriate to this section than the definition at 40 CFR 122.2.

4. Maximum Timeframe

The Great Lakes Guidance proposes a maximum three-year limit on the duration of variances, subject to possible renewal. This is intended to reinforce the triennial review required of all water quality standards in section 303(c) of the Clean Water Act. EPA's 1979 Guidance clearly indicated that variances must be reviewed every three years. Some States and Tribes use the triennial review process to accomplish this review; however, this is not universal and triennial reviews are often delayed. EPA believes that the most effective way to assure that variances get a detailed review at the prescribed interval is to require them to actually expire at no greater than three-year intervals.

5. Conditions to Grant a Variance

Variances under the Great Lakes Guidance are applicable if any of five specified types of water body conditions exist and/or the affected community would encounter substantial and widespread economic and social impacts as a result of the point source having to install controls beyond technology-based requirements. The permittee must also make two other demonstrations.

The first demonstration would be that the requested variance is consistent with State or Tribal antidegradation procedures. This requirement would prevent a variance that would result in a lowering of actual water quality for any pollutant where water quality for that pollutant does not support either the designated or existing uses or in any water constituting an outstanding national resource as proposed at section I.C of appendix E of part 132. This provision would also prevent dischargers from avoiding the proposed requirements of section I.B of appendix E of part 132 in high quality waters by requesting a variance rather than conducting an antidegradation demonstration. In most instances, variances are requested where water quality standards are already not being met. In addition, the requirement at procedure 2.F.1 of appendix F requiring dischargers to maintain the level of treatment achieved under the previous permit would normally prevent a discharger from being granted a variance that would result in a lowering of water quality. The antidegradation showing would simply demonstrate to the State and public that either a concurrent antidegradation question is not at issue or that, if one is, the regulatory provisions for antidegradation are being met. EPA requests comment on whether this demonstration is appropriate.

Second, the applicant would be required to demonstrate the extent of any increased risk to human health and the environment associated with compliance with the variance compared to the original water quality standards, and the State or Tribe would be required to find that any such increased risk is consistent with the protection of the public health, safety and welfare before granting a variance. Because variances are from water quality standards that meet the goals and requirements of the Clean Water Act, this language is intended to ensure that the general requirement of section 303(c)(2)(A) of the CWA (i.e., such standards shall be such as to protect the public health and welfare) is met even though specific protective criteria may be temporarily exceeded.

The permittee has the sole responsibility to provide sufficient relevant information, pursuant to State or Tribal requirements, to make a variance demonstration for the pollutant(s) in question. Failure of the permittee to make the demonstration or to provide sufficient information in the submitted demonstration shall result in a State denial of the variance.

6. Timeframe to Submit Application

The proposed Guidance would allow initiation of the source-specific variance process after the controls based upon water quality standards are imposed in NPDES permits since that is the time when a point source discharger knows the exact requirements that will be imposed and is in the best position to assess whether those limits can be attained. This would reduce the number of variance requests by avoiding protecting requests. Comment is requested on whether it would be more appropriate to require initiation of the variance process within 60 days of a proposed permit. If a variance is granted after the effective date of the water quality-based NPDES effluent limitation in question (e.g., after completion of any evidentiary hearing during which the limitation was stayed and after the compliance date for the limitation), then the permittee will have to demonstrate satisfaction of the anti-backsliding requirements of section 402(o) of the CWA before the permit can be modified to include a less stringent effluent limitation. That demonstration may be based on either section 402(o) or section 303(D)(4)(A).

7. Public Notice of Preliminary Decision

The proposed Guidance would provide the public an opportunity to be involved at two times: First, during the comment period associated with the notice of receipt of the variance request; and second, during the public notice of the modification of the permit. In addition, the requirement that variances be appended to State water quality standards rules ensures that the public is made aware of which variances have been granted. Both public notices should contain a clear description of the

impact of the variance upon achieving water quality standards in the affected stream segment.

The following is a summary of the elements that EPA would expect to be made available to the public in order to meet the public notification requirements of the water quality standards regulation and the proposed Guidance. These items would not need to be included in detail in the public notice; however, the public must be made aware of their existence and of how and where they may be obtained.

a. A statement that the action must comply with the State's or Tribe's variance procedures and description of those procedures.

b. The permittee's demonstration, including the rationale for the requested variance and the extent of any increased risk to human health and the environment associated with the variance.

c. In addition, for the public notice for the modification of the NPDES permit, the public comments and public hearing record pursuant to procedure 2.E of appendix F, and the State approval pursuant to procedure 2.F appendix F of the proposed Guidance.

EPA requests comment on whether the public notice requirements in this proposal are adequate to allow the public to be fully involved in the State water quality standards variance process and, if not, what requirements would be adequate.

8. Final Decision on Variance Request

The proposed Guidance would allow the State's or Tribe's final decision on the variance request to be an approval, partial approval, or disapproval. This decision would be required to include all NPDES permit conditions needed to implement the parts of the variance approved. These conditions would be designed to assure that: The permittee minimizes, to the maximum extent possible, exceedance of the underlying water quality standards by implementing the level of treatment currently achievable (conditions requiring effluent limitations at least as stringent as those achieved under the previous permit); the permittee makes reasonable progress toward attaining the water quality standards as envisioned in the 1983 preamble, through appropriate conditions (such as the establishment of a capital improvements fund and continued investigations of treatment technologies, process changes, pollution prevention, wastewater reuse and/or other techniques that will reduce the level of the pollutant or result in compliance by the permittee with the WQS and submission of reports on the investigations at such time specified by the State), and effluent limits sufficient to protect water quality standards are in effect upon expiration of the variance.

9. Incorporating State- or Tribal-Approved Variance Into Permit

Once the variance is granted, the appropriate NPDES permitting authority would be required to modify the NPDES permit to incorporate all NPDES permit conditions determined to be necessary to implement the variance.

10. Renewal of Variance

The proposed Guidance would require the permittee to apply for a variance renewal and make a new showing of justification, no later than the required submission of a permit application for a NPDES permit, or 60 days prior to the expiration of the variance, whichever occurs earliest; variances would not be automatically renewed. As part of the renewal application, the permittee must be required to demonstrate that it has met the NPDES permit conditions implementing the existing variance. The same public notice requirements for the initial issuance of a variance would apply to the renewal. Permittees not demonstrating compliance with these conditions would not be eligible for variance renewal. EPA requests comment on the sufficiency of the proposed renewal requirements.

11. EPA Approval

Variances are modifications of State or Tribal water quality standards and are, therefore, subject to EPA review and approval. Like other water quality standards changes, variances are effective when adopted (under the terms of the adoption), whether or not EPA review is complete. For EPA to conduct an adequate review, sufficient information must be submitted. Procedure 2.I of appendix F would set out the timeframe and substantive requirements for that submittal. EPA's review would follow the procedures of 40 CFR 123.44 and 40 CFR 131.21. EPA requests comment on the sufficiency of the proposed information requirements in this section as well as the appropriateness of the proposed timeframes.

12. State or Tribal Water Quality Standards Revisions

Because water quality standards variances are modifications of water quality standards, the proposed Guidance would require the State or Tribe to append the State- or Tribal-approved variances to the State's water quality standards. EPA has traditionally required water quality standards variances to be granted through the water quality standards adoption process. This requirement is intended to ensure that: the public is made aware that a water quality standards change is under consideration and has sufficient opportunity to comment on the action; the State or Tribal water quality standards document accurately reflects the criteria that will be used to derive effluent limitations and other water quality-based controls; and water quality standards variances are submitted to EPA for review and approval/disapproval under section 303 of the CWA.

There was considerable concern expressed by the States, during the preparation of the proposed Guidance, that this requirement would make water quality standards variance adoptions so lengthy that variances would be essentially unusable for granting appropriate relief to dischargers in a timely manner. EPA and the Technical Work Group recognized this concern and have, through the public participation and EPA review and approval requirements of the proposed Guidance, met the substantive requirements of a water quality standards action while allowing a water quality standards variance be appended to, rather than adopted in, the State or Tribal standards. Thus, the proposed Guidance allows the Great Lakes States or Tribes to grant water quality standards variances without requiring that those variances go through their usual water quality standards adoption process. EPA requests comment on whether the proposed Guidance adequately meets the intent and substantive requirements for State or Tribal adoption of variances as changes to water quality standards.

The proposed Guidance contains no timeframe under which the State and Tribes would be required to append the variance to the standards. EPA requests comment on whether such a mandatory timeframe is necessary, and if so, what that timeframe should be.

13. Consistency With the CWA and Conformance With the GLWQA

The CPA requires EPA to develop, *inter alia*, guidance on procedures that States must use to implement the Guidance's water quality criteria in the Great Lakes System. The CPA states that the proposed Guidance shall be no less restrictive than the provisions of the Clean Water Act, and shall conform with the objectives and provisions of the Great Lakes Water Quality Agreement. The variance provision contained in the

proposed Guidance complies with these requirements, as explained below.

a. *Consistency With the Clean Water Act.* It is the goal of the Clean Water Act to achieve, wherever attainable, water quality which provides for the protection and propagation of fish, shellfish, and wildlife and provides for recreation in and on the water. 33 U.S.C. 1251(2). EPA's regulation found at 40 CFR 131.10(g) addresses the above language's phrase wherever attainable. To fully understand the proposed Guidance on water quality standards variances, one must start with this provision. Basically, under the CWA's regulatory structure, water quality criteria are set by States or Tribes at levels which are directed at achieving a stream's designated use(s). 40 CFR 131.10(g) sets forth the procedure by which States or Tribes may remove a stream's designated beneficial use, under specified conditions. Removing a stream's designated use due to the unattainability of that use may have the effect of lowering the water quality criteria for the subject stream segment unless a use with more stringent criteria is designated.

Limiting the applications of 40 CFR 131.10(g) is 40 CFR 131.10(h), which states:

States may not remove designated uses if:

(1) They are existing uses (existing uses are those uses actually attained in the water body on or after November 28, 1975, whether or not they are included in the water quality standards. 40 CFR 131.3(e).), as defined in § 131.3, [i.e.,] unless a use requiring more stringent criteria is added; or

(2) Such uses will be attained by implementing effluent limits required under sections 301(b) and 306 of the CWA and by implementing cost-effective and reasonable best management practices for nonpoint source control.

The practical effect of removing a stream's designated use is that the water quality criteria (which are the bases for limiting the discharge of pollutants into that stream) are revised to meet the remaining or revised use(s). Removing or modifying a beneficial use, therefore, may effect a relatively widespread and permanent lowering in water quality criteria.

No use removal provision exists in the proposed Guidance because, in general, permanent removal of CWA goal uses would have little or no effect on the applicable water quality criteria. Instead, as explained in sections III, V and VI of this preamble, water quality criteria or methodologies for the protection of aquatic life, wildlife and human health are applicable basin-wide, with limited exceptions (see section VIII.A on site-specific modifications).

In effect, the variance provision included in the proposed Guidance, in addition to providing the variance function provided for in 40 CFR 131, provides a method, appropriate to the Great Lakes, analogous to the Federal use removal provision. Consistent with this approach, the proposed Guidance basically incorporates the language from 40 CFR 131.10(g), with minor modifications. The difference, of course, as mentioned previously in the preamble discussion, is that the application of the factors in the proposed Guidance will only result in a temporary variance for individual dischargers and pollutants rather than resulting in a removal or modification of a designated use and possible change of associated criteria for the entire water body segment. For this reason and viewed in context, therefore, the proposed Guidance is not less stringent than what the CWA currently allows.

Secondly, it will be recalled that the Water Quality Standards Regulation (40 CFR Part 131) does not require, but only indicates the allowability of, State or Tribal variance procedures. The proposed Guidance is consistent with this approach because the proposed Guidance does not require a State or Tribe to have variance procedures, but rather only specifies what the variance provision should be consistent with if the State or Tribe decides to adopt one.

Finally, as outlined previously in the preamble discussion, the proposed Guidance is fully consistent with the EPA's prior opinions and guidance documents on State variance provisions. (e.g., the Decision of the General Counsel No. 58 dated March 29, 1977; Preamble to the 1983 Revisions to the Water Quality Standards Regulation; and the 1985 Guidance on Variances issued by the Director of the Office of Water Regulations and Standards, which is available in the administrative record for this rulemaking.)

b. *Conformance With the Great Lakes Water Quality Agreement.* Like the Clean Water Act, the purpose of the Great Lakes Water Quality Agreement (GLWQA) is to restore and maintain the chemical, physical and biological integrity of the waters it addresses. Similar to the Clean Water Act, the Agreement is structured to achieve this purpose by requiring the elimination or reduction to the maximum extent practicable of discharges of pollutants into the Great Lakes System. See Article II, Purpose.

As indicated by the language, to the maximum extent practicable, the GLWQA recognizes the need for flexibility in addressing requirements which, if imposed, would be impracticable. In particular, the Agreement contains language in Article IV, Specific Objectives, which explicitly recognizes situations in which achievement of Specific Objectives cannot be attained. These provisions are reasonably read as delineating situations in which temporary variances are permissible. Article IV, Specific Objective 1, contains the following provisions:

(e) The Parties recognize that in certain areas of inshore waters natural phenomena exist which, despite the best efforts of the Parties, will prevent the achievement of some of the Specific Objectives. As early as possible, these areas should be identified explicitly by the appropriate jurisdictions and reported to the International Joint Commission.

(f) The Parties recognize that there are areas in the boundary waters of the Great Lakes System where, due to human activity, one or more of the General or Specific Objectives of the Agreement are not being met. Pending virtual elimination of the persistent toxic substances in the Great Lakes System, the Parties, in cooperation with State and Provincial Governments and the Commission, shall identify and work toward the elimination of:

(i) Areas of Concern pursuant to Annex 2; and

(ii) Critical Pollutants pursuant to Annex 2; and

(iii) Point Source Impact Zones pursuant to Annex 2.

These provisions clearly recognize that objectives may not be attainable due to natural phenomena and/or human-caused conditions. In the case of an area affected by natural phenomena, the Agreement requires such areas to be identified and reported to the International Joint Commission. In the case of areas affected by human activity, the Agreement requires the Parties work toward elimination of such conditions areas by identifying and eliminating Areas of Concern, Critical Pollutants and Point Source Impact Zones.

The provisions of Article IV as well as the practicable language in Article II of the Agreement, are reasonably read as allowing provision for temporary variances from water quality standards. The variance provision in the proposed Guidance specifies certain naturally occurring and human-caused sources of pollution which could justify temporary relief from standards. The widespread social or economic impact variance addresses the Agreement's language that discharges must be reduced or eliminated where practicable.

It is EPA's position that the variance provision included herein conforms with the GLWQA because it is limited

to situations where the discharger's or the stream's compliance with water quality standards is not practicable. Additionally, the proposed Guidance requires that reasonable progress be made toward compliance with water quality standards. This requirement parallels the requirement of Article IV(f) of the GLWQA, that the Parties must work toward the elimination of the sources of pollution in the areas not complying with the objective of the GLWQA.

14. Options Considered

a. One option considered by the Technical Work Group when developing the proposed Guidance would have: allowed the State or Tribe to request additional information from the permittee within 30 days after receiving the variance application and given the permittee an additional 30 days to provide the additional information; required the Great Lakes State or Tribe to issue the preliminary decision on the variance request within 120 days of receipt of the completed application and provide a 30 day public comment period on the preliminary decision, and; required the State or Tribe to issue a final decision within 90 days of the expiration of the public comment period or the receipt of additional information discussed above. Failure of the permittee to provide the additional information in the time allotted would have resulted in the denial of the variance. The proposed Guidance does not contain these time constraints because it is EPA's opinion that existing State or Tribal administrative procedures provide both sufficient freedom to request additional information and sufficient requirements to act in a timely manner.

EPA requests comment on whether the proposed Guidance requires the Great Lakes State or Tribe to act in a sufficiently timely manner on variance applications or whether time constraints similar to the above are necessary. EPA also requests comment on whether the proposed Guidance allows the State or Tribe sufficient flexibility in collecting the information necessary to make a defensible decision or whether an explicit period for requesting additional information is advisable.

b. Another option considered by the Technical Work Group would require NPDES permitting authority to initiate any applicable NPDES permit modification in procedure 2.G of appendix F, of the Guidance within 60 days after granting the variance. The proposed Guidance does not contain this time constraint because it is EPA's opinion that existing State or Tribal administrative procedures provide sufficient requirements to act in a timely manner.

EPA requests comment on whether the proposed Guidance requires sufficiently timely State or Tribal action in initiating a permit modification in response to an approved water quality standards variance.

c. Another option considered by the Technical Work Group allowed variances based only on procedure 2.C.6 of appendix F, widespread social and economic impact. EPA chose to expand the allowable bases for water quality standards variances to include those in procedures 2.C.1 through C.5 of appendix F, where water body conditions may warrant short-term relief for point sources to be consistent with EPA's 1985 Guidance and section 510 of the CWA. In addition, EPA found that these additional bases for a water quality standards variance, especially procedures 2.C.1 and 2.C.3 of appendix F, were necessary to provide States with sufficient flexibility to address the issue of unreasonable water quality-based effluent limits resulting from ubiquitous pollutants in a facility's intake water (see discussion in section VIII.E of this preamble.)

EPA requests comment on whether the factors for the granting of variances to water bodies in the Great Lakes System should be different than those for granting variances in other waters of the United States and, if so, the scientific rationale for such a difference (see also section o.ii, below). EPA also seeks comment on whether the requirements under procedure 2.C of appendix F that cost-effective and reasonable best management practices for nonpoint source control be implemented should, as proposed, be limited to best management practices the permittee can implement or should include all best management practices required by a State or Tribal regulatory program for the area in question.

d. Another option considered by the Technical Work Group required the State or Tribe to provide for an additional period of public comment. This public comment period would have been initiated within 30 days of receipt of a completed variance application and would have given the State public input prior to making a preliminary decision on a variance request. EPA has not included this additional public comment period in the proposed Guidance because two opportunities for public comment are provided, first, during the comment period associated with the notice of receipt of the variance application, and second, during the public notice of the modification of the permit, and because an additional comment period was considered to be unnecessary and pose an undue administrative burden on the States.

EPA requests comment on whether there is a need for public comment early in the variance process and, if so, how that need can be met without posing an undue administrative burden on the State and Tribal governments.

e. Another option considered by the Technical Work Group would have required States and Tribes to public notice variance applications in all eight Great Lakes States. The proposed Guidance requires the Great Lakes States and Tribes to notify the other Great Lakes States and Tribes of the preliminary decision. EPA decided against proposing to require the wider public notice requirement because it was considered to be unnecessary, to pose an undue administrative burden on the States and to have the potential to unreasonably lengthen the variance review and approval process.

EPA requests comment on whether wider public notice is necessary and, if so, how it can be accomplished without posing an undue administrative burden on the States and without having the potential to unreasonably lengthen the variance review and approval process.

15. Request for Comments

EPA specifically invites public comment on these additional issues that received discussion during the drafting of this proposal:

a. Although the proposed Guidance emphasizes that variances are based on water quality standards, these variances are implemented for point sources in the permitting process. The three-year expiration of water quality standards variances is based on the triennial water quality standards review cycle and makes sense for a provision that requires a modification of standards. However, NPDES and State- or Tribally-authorized permits are normally granted for five years. Because the variance would be implemented in a permit, it has been suggested that the variance requirements include a provision allowing variances to be granted for up to five years, with a reassessment after three years. EPA invites comment on this suggestion.

b. Some States have suggested using criteria similar to the first five elements (procedures 2.C.1 through 2.C.5 of appendix F of part 132) to establishing variances to use classifications for entire water body segments or portions of water body segments. This could be done, for example, where historic mining practices have impaired water

quality and designated uses, but the State or Tribe has considered the problems correctable within a reasonable planning period (the 20-year, section 208 planning period, for example). In such situations, the State maintains goal uses and underlying criteria while recognizing existing ambient conditions by adopting ambient-based criteria which have specific expiration dates. This approach allows a State or Tribe to incorporate the criteria modified by the water body variance into all appropriate NPDES permits on the specific water body. This approach might be used to relieve dischargers from the burden of demonstrating that individual variances are appropriate and allows multiple dischargers to pool their resources to make a demonstration that a variance based solely on water body conditions is appropriate. This approach might also decrease the State or Tribal burden of reviewing multiple applications for discharger-specific variances based on water body conditions.

EPA believes that the water body variance may provide a way of applying the use-based 40 CFR 131.10(g) elements in a manner that makes sense and meets the objectives of the water quality standards variance policy. EPA requests comment on this bifurcated approach of dividing variances into two categories: water body variances to which the first five elements (procedures 2.C.1 through 2.C.5 of appendix F) apply, and discharger-specific variances to which the substantial and widespread economic and social impact element (procedure 2.C.6 of appendix F) applies.

EPA additionally requests comment on whether it would be appropriate to require, as a condition to granting the water body variance referenced above, that a TMDL be developed for the water body at issue based on pre-variance criteria. See section VIII.C on TMDLs, especially phased TMDLs at section VIII.C.2.b, for further information on what this requirement would entail. The rationale for conditioning a water body variance with the TMDL requirement is that, before all dischargers are given relief from applicable water quality standards, there should be a plan in place through the TMDL process to ultimately achieve the applicable water quality standards. EPA also requests comment on the maximum timeframe for completing such a required TMDL if one should be required. For example, making a water body variance non-renewable would have the effect of requiring a TMDL be developed within three years (or by the expiration of the variance). Permits could then be written to be in conformance with the TMDL and a variance would no longer be necessary.

c. Because variances may not be granted if they do not comply with the proposed Antidegradation Policy at 40 CFR 132, appendix E, a variance will not be allowed if it results in lowering of existing water quality unless in compliance with the antidegradation requirements. Because of this restriction, because variances are subject to EPA review, and because EPA will consult with the Fish and Wildlife Service regarding approvals of water quality standards pursuant to a recently signed agreement, it does not appear that variances would be granted which would jeopardize threatened or endangered species. EPA requests comments on whether additional safeguards are needed to protect threatened or endangered species.

d. Procedure 2.C.6 of appendix F allows a water quality standards variance to be granted if controls would cause widespread social or economic impact. EPA has traditionally used many of the same economic measures to determine social or economic impact when evaluating use removal and water quality standards variance requests as it uses to determine important economic or social development when evaluating the allowable lowering of water quality under the antidegradation policy. EPA requests comment on whether further guidance on how to determine social or economic impact is needed, and, if so, whether social or economic impact should be interpreted similarly to important economic or social development as discussed in section VII.F.5 of this preamble (Antidegradation Demonstration). EPA also requests comment on whether further guidance is necessary on the interpretation of widespread, and, if so, whether the determination of widespread should be similar to the determination of economic area discussed in section VII.F.5 of this preamble (Antidegradation Demonstration).

e. As written, the variance provision only provides for variances for applicants for NPDES permits, not section 404 permits for the discharge of dredged or fill material. As a practical matter, few if any section 404 dischargers would be eligible for a water quality standards variance, as envisioned in the proposed Guidance, because most section 404 discharges are short-term, one-shot activities and therefore the applicants would be new dischargers or recommencing dischargers. EPA solicits comments on whether there is any need to expand the proposed variance procedure to address non-NPDES permits.

C. Total Maximum Daily Loads

1. Background

One approach to achieving the water quality goals of the Clean Water Act is to ensure that technology-based effluent limitations are established in NPDES permits. Such limitations are based on: (1) Effluent guidelines established by EPA for major industrial categories under section 304 of the Clean Water Act, (2) the best professional judgement of permit writers for industrial point sources not subject to effluent guidelines or, (3) secondary treatment requirements for POTWs. Where existing technology-based limitations, together with other State or Federal pollution controls are insufficient to attain and maintain water quality standards, additional water quality-based controls are necessary. Section 303(d) of the Clean Water Act requires the establishment of total maximum daily loads (TMDLs) for waters that are not expected to meet applicable State water quality standards despite implementation of existing or planned pollution controls.

2. National Approach

a. *General Approach to TMDL Development.* EPA National policy on the development, review and approval of TMDLs is contained in the Water Quality Planning and Management regulation, 40 CFR part 130. Additional guidance is provided in the "Technical Support Document for Water Quality-based Toxic Control," (TSD) EPA 505/2–90–001, March 1991 and the "Guidance for Water Quality-based Decisions: The TMDL Process," EPA 440/1–91–001, April 1991.

TMDLs are established to meet the water quality criteria and designated uses that apply to a given water body. The TMDL quantifies the maximum allowable loading of a pollutant to a water body, and allocates this loading capacity to contributing point and nonpoint sources (including natural background) such that water quality standards will not be violated. A TMDL must incorporate a margin of safety (MOS) that accounts for uncertainty about the relationship between pollutant loads and water quality. TMDLs may involve a single pollutant source or multiple sources (e.g., point sources and nonpoint sources) and may be established for geographic areas that range in size from large watersheds to relatively small water body segments. EPA encourages the development of TMDLs that reflect tradeoffs between

point and nonpoint sources where such tradeoffs achieve the desired environmental result and are cost-efficient.

EPA guidance suggests that protective assumptions be used in developing TMDLs and recognizes that use of such conservative assumptions may provide the MOS required. Where necessary, an additional margin of safety can be allocated as a separate component of the TMDL.

b. *Phased TMDLs.* The CWA assigns the primary role for TMDL development to the States and the Indian Tribes. EPA provides guidance to the States and Tribes and is required to review TMDLs the States and Tribes develop. If EPA disapproves a State or Tribal TMDL, the Act authorizes EPA to establish a revised TMDL.

Generally, a phased approach to TMDL development should be used when significant nonpoint source or complex water quality problems involving many sources are present. Under a phased approach, a TMDL is developed and implemented using best available information, professional judgement and a margin of safety that reflects uncertainties. The phased TMDL incorporates a monitoring plan and a schedule for assessing the attainment of standards after the implementation of pollution controls. If standards are not attained after implementation of the TMDL, the data obtained through the monitoring program can be used to develop a revised TMDL.

TMDLs established using the phased approach allow EPA and the States to move forward and implement water quality-based control measures when limited information is available. Thus, for example, TMDLs that address pollutants originating primarily from nonpoint sources can be established using the phased approach even though the ability to analyze and model nonpoint source loadings, pollutant fate and transport and actual water quality effects is not as developed as the ability for point source loadings. Under the phased approach the statutory requirements of section 303(d) can be met even in the absence of extensive data on cause and effect relationships and the effectiveness of control measures, particularly best management practices (BMPs) for nonpoint sources.

One situation where a phased approach is used is where a TMDL incorporates nonpoint source allocations based on future implementation of nonpoint source control requirements. Such phased TMDLs must include documentation concerning the nonpoint source control implementation plan and the basis for projecting nonpoint source load reductions. EPA will approve such TMDLs only when there is a reasonable likelihood that LAs will be achieved in a reasonable time frame.

A phased TMDL could be used in situations where a point source is discharging to a water that does not attain standards due in part to nonpoint source loadings. One option for TMDL development would be to identify BMPs that are expected to reduce nonpoint loadings such that the nonpoint source contributions alone would result in attainment of water quality standards with a margin of safety. If a State or a Tribe implements a program reasonably anticipated to result in BMP implementation, it could establish LAs in a TMDL that reflect load reductions expected through BMP implementation. The WLA in the TMDL for the point source could allow a discharge at a concentration equal to (or in some cases greater than) criteria or values.

EPA's approval of TMDLs (including phased TMDLs) is case-specific, and depends on a review of the technical assumptions and procedures used to develop the TMDL and, as noted above, whether it is reasonable to expect that anticipated nonpoint source controls will be implemented and be effective.

c. *Pollutant Degradation.* One factor that needs to be considered in establishing TMDLs is the possibility of degradation of a pollutant after it is released to surface waters. If there were no degradation reactions taking place in aquatic ecosystems (i.e., if all pollutants behaved conservatively), every pollutant released to the environment would be present at some location. However, there are natural physical, chemical and biological processes that serve to degrade some pollutants and ameliorate their impacts. These natural processes include hydrolysis, oxidation, photo-transformations (photolysis), and biological transformation. Degradation is different from pollutant transport, which simply involves the movement of a chemical in the environment and is discussed below.

Existing EPA policy regarding the environmental fate of pollutants is that where data are available to support estimation of degradation rates, it is appropriate to include these calculations when establishing TMDLs. Two EPA references providing information on environmental fate are Processes, Coefficients and Models of Simulating Toxic Organics and Heavy Metals in Surface Waters (EPA/600/3–87/015; June 1987) and Water-Related Environmental Fate of 129 Priority Pollutants (EPA–400/4–79–029a,b; December 1979).

d. *Pollutant Transport.* Pollutant transport includes dispersion of pollutants in ambient waters, and the movement of pollutants from the water column to bottom sediments or to the air. Transport within the water column is relevant in establishing TMDLs where States require criteria attainment at the edge of allowed mixing zones. In such circumstances it is necessary to calculate pollutant concentrations that will exist at the edge of the mixing zone as a result of discharge-induced mixing, currents and turbulence in the receiving waters and pollutant dispersion. Similarly, volatilization that occurs before the edge of a mixing zone can be considered in determining the amount of discharge that will not cause an exceedance of water quality standards at the edge of an applicable mixing zone. Transfers to sediment may be taken into consideration in establishing a TMDL, but care must be taken to also account for pollutant release from sediments.

3. Development of the Proposed Guidance

a. *The Proposed Guidance.* The Great Lakes Technical Work Group attempted to devise a single, consistent approach for developing TMDLs to be used by all States and Tribes in the Great Lakes System. Current practice in the eight Great Lakes States includes distinct technical procedures and program approaches which differ in scope, scale, emphasis and level of detail. Although there was broad general agreement on dealing with TMDL development for Open Waters of the Great Lakes (OWGLs), the technical work group found it difficult to agree upon a single set of procedures and processes to establish TMDLs for tributaries. The underlying reason for the inability to reach a technical consensus is that there are at least two views on how to meet the Clean Water Act's requirements for establishing TMDLs for tributaries on a large basin scale. One focuses first on evaluating the basin as a whole, followed by site-by-site adjustments. The other focuses initially on evaluating limits needed for individual point sources with supplemental emphasis on basin-wide considerations as necessary. Both approaches are consistent with the Clean Water Act, but result in different methodologies for TMDL development. Each option provides that TMDLs be established on a case-by-case basis by the authorities responsible for developing TMDLs.

The Steering Committee proposed to include two options (Option A and Option B) in the proposed Guidance and

to solicit comments widely on all aspects of both options. Option A is presented as procedure 3A of appendix A to part 132; Option B is presented as procedure 3B. Option A utilizes the first approach described above and is similar to the approach currently used by New York State. Option B utilizes the second approach described above and is similar to the approach used by several States within EPA Region V. Option B includes specific formulae and assumptions to be used in deriving TMDLs.

The proposed Guidance is not intended to be a completely comprehensive set of provisions addressing all aspects of section 303(d) implementation by the States. Accordingly, such matters as required submission by States and Tribes of lists of waters needing TMDLs, are not addressed in the proposed Guidance. Current National regulations at 40 CFR part 130, would continue to apply in the Great Lakes States.

Explicit guidance on deriving nonpoint source load allocations and implementing nonpoint source controls are not included in the proposed Guidance. While both options provide general guidance on how TMDLs should consider nonpoint source loadings, existing EPA regulations and technical guidance should be used for these purposes.

b. *Overview of Option A and Option B.* Both options propose procedures for establishing TMDLs for open waters and connecting channels and separate procedures for establishing TMDLs for tributaries to the Great Lakes. Both options contain general conditions applicable to all TMDL development, and special conditions regarding control of bioaccumulative chemicals of concern (BCCs). Options A and B are essentially the same with respect to general conditions of TMDL development, control of BCCs and the development of open waters and connecting channels.

The main differences between the two options exist in the development of TMDLs for tributary discharges. These differences are primarily in the development of wasteload allocations and focus on the degree of specificity contained in the procedure and the use of mixing zones and margins of safety in each option. Option A and B are discussed in greater detail below.

4. General Conditions of Application

Options A and B both contain the same ten general conditions of application. The general conditions apply to every TMDL established under the GLWQI and assure that TMDLs employ consistent methodologies, analytical approaches and assumptions.

a. *General Condition 1.* General condition 1 establishes that, at a minimum, TMDLs must be established for each pollutant for which it is determined that there is a reasonable potential that a discharge will cause or contribute to an exceedance of WQS and where the sum of existing point and nonpoint source (including natural background) loadings exceeds the loading capacity of the water under investigation minus any margin of safety. For additional guidance on when TMDLs must be prepared, see 40 CFR 130.7.

b. *General Condition 2.* General condition 2 establishes that a TMDL for a given pollutant must implement all criteria for that pollutant that are applicable to the water body in question. As a practical matter, this will normally involve identification of the most stringent applicable criterion and development of a TMDL based on its implementation. General condition 2 also establishes that a TMDL must consider point and nonpoint sources and that the sum of the WLAs for point sources, LAs for nonpoint sources, and any specified MOS and reserve capacity for future growth, shall not exceed the loading capacity. This general condition assures TMDLs will provide for attainment of water quality standards.

c. *General Condition 3.* General condition 3 recognizes that TMDLs may be developed for downstream waters that will include WLAs for sources already covered by a TMDL of different geographic scope. For example, a source-specific TMDL may already be in place when a basin TMDL is developed. The condition requires that WQBELs in NPDES permits be consistent with the most stringent of the WLAs included in any EPA-approved or EPA-established TMDLs. This assures that water quality standards will be met throughout a drainage basin.

d. *General Condition 4.* General condition 4 requires that each TMDL describe the manner in which a MOS is provided and that MOSs be established either by setting aside a portion of the loading capacity or by using conservative modelling assumptions in deriving the TMDL.

e. *General Condition 5.* General condition 5 provides that States may employ the provisions of section 510 of the CWA to establish TMDLs more stringent than those developed pursuant to the proposed procedures. This condition simply recognizes the reserved right of the States to require more stringent controls than those required under the CWA.

f. *General Condition 6.* General condition 6 establishes that TMDLs must consider contributions to the water column from sediments inside and outside mixing zones. Although TMDLs are calculated on the basis of pollutants in the water column, all sources of pollution, including sediment re-release to the water column, must be considered during the establishment of the TMDL.

g. *General Condition 7.* General condition 7 clarifies that the implementation procedure for TMDLs does not include explicit methods or requirements for determining controls necessary to ensure attainment of water quality standards during wet weather events. Nonpoint sources, storm water discharges and combined sewer overflows can typically be expected to have the greatest impact on receiving waters during storm events. While implementation procedures specific to wet weather events are not included in this Guidance, TMDLs must consider pollution resulting from these wet weather events. The procedures contained in the proposed Guidance may be appropriate in some case-specific applications.

h. *General Condition 8.* General condition 8 establishes the procedure for determining representative background concentrations of pollutants. Procedures and assumptions for calculating or identifying background assure that background concentrations will be consistently considered as TMDLs are established. The first step in this process will be selecting one of three possible data sets: Representative caged fish tissue data, representative ambient monitoring data, or representative poliutant loading data. While ambient monitoring data are generally preferred over other data sources, there may be instances where the ambient data are not available, or because of limits in analytical detection methods, are not as informative or reliable as either caged fish tissue or pollutant loading data. Care must be taken to ensure that the data represent, or are adjusted to represent, ambient conditions of concern in the TMDL development process. After a data set is selected, a geometric mean is taken of representative data points.

With respect to pollutant loading data, the geometric mean is taken of pollutant loading data from individual sources; the individual means are then added to estimate total loading to the receiving water. Background concentration is calculated by dividing total loadings by the volume of water available at the appropriate design flow (which will vary depending on the

criterion being implemented through TMDL establishment) at the point immediately upstream of the watershed, water body or water body segment for which the TMDL is being established.

Calculating the background concentration of a pollutant using caged fish tissue data or ambient monitoring data generally does not require a separate determination of the pollutant's degradation or transport upstream of the water body for which the TMDL is being prepared. However, when actual loadings are used to derive background concentration, the assumption of conservation of mass throughout the segment of interest may not be accurate for some pollutants. Pollutant degradation or transport studies may show that the substance does not contribute to a problem after a certain point downstream from the original point of introduction into the water body. The Steering Committee's proposal on environmental fate prohibited accounting for the degradation or transport of a pollutant that occurs outside of the mixing zone for a point source, but that was coupled with the Steering Committee's choice of ambient monitoring data to determine background. EPA believes that accounting for degradation and transport outside of the mixing zone may be appropriate in circumstances when background concentrations are being calculated using actual loadings to the system of interest. Accordingly, the proposed Guidance provides for consideration of pollutant degradation and transport in such circumstances. EPA invites comments on this issue.

Individual data points may not be representative for a variety of reasons. Best professional judgement will be used to determine which data points are acceptable. For example, a data point may not be acceptable if reported as below detection if the detection level itself is not reported. The permitting authority should also consider detection levels and quantification levels of data when determining what data are acceptable. Recent data with improved detection or quantification levels may be acceptable, while some older data with poorer detection or quantification levels may render it unacceptable.

Care should be exercised in determining what fish tissue data are representative of background pollutant concentrations. When using caged fish tissue data to calculate background concentrations, the geometric mean of representative fish tissue analysis is taken and that value will generally be divided by the bioaccumulation factor calculated for the pollutant in question pursuant to the proposed methodology in appendix B of part 132 to yield estimated ambient concentrations. However, where fish tissue data from a single species are used to calculate background calculations, and where bioaccumulation data exist for that species, it may be more appropriate to use a species-BAF rather than a BAF derived through the methodology in appendix B. To be acceptable, the fish must have lived within the geographic area long enough to have reached or approached steady state conditions in terms of bioaccumulation. Steady state occurs when the level of pollutant uptake is approximately equal to the level of pollutant elimination from the fish. EPA guidance on these calculations and considerations is provided in Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual (USEPA, September, 1989, EPA–503/8–89–002). EPA intends to provide further guidance through finalization of a draft document entitled Assessment and Control of Bioconcentratable Contaminants in Surface Waters (March, 1991).

Within a given data set, some data points may indicate that the pollutant was not present at levels capable of being detected by the analytical method used. For these data points the true concentration of the pollutant could be anywhere between zero and the detection level of the method. Other data points may indicate that the pollutant was detected, but at levels below which the analytical method is capable of reliable quantification. For these pollutants, the true concentration will be between the detection level and the quantification levels of the analytical method. Finally, there may be data points showing reliably quantified levels of the pollutant. Consistent with the Steering Committee's intent, the proposed Guidance would require, that all data points showing that the pollutant is not present at the detection level be considered to represent a concentration of one-half of the reported detection level, provided that at least one data point is above the level of detection. Similarly, for data points that show that the pollutant is present at concentrations between the detection level and the quantification level, the proposed methodology would provide for use of a concentration equal to the mid-point between the reported detection level and the reported quantification level. While this condition was not addressed by the Steering Committee proposal, EPA believes that all these conditions are necessary and appropriate for dealing with values that are not detected or not quantified.

EPA believes that it is necessary to accord some weight to data points below the detection level or quantification level in calculating a geometric mean; to do so requires the selection of a concentration value within the range of possible values. EPA is proposing to use one-half of the reported detection level and also the mid-point between the reported detection level and reported quantification level as reasonable estimates of actual concentrations. Where data are described as below the detection level, EPA could also have proposed to use either zero or the reported detection level. Use of the reported detection level in such instances would result in the lowest WLA for point sources, and while certainly protective of water quality, may require a greater reduction in point source loadings than necessary. Use of zero in such instances would result in the greatest WLA for point sources but may not assure the attainment of water quality standards. Because there is no way to reliably quantify pollutant concentrations below the detection level, EPA believes that using one-half of the reported detection level is a reasonable balance of the available options.

The proposed Guidance specifies, however, that where all acceptable available data points in a data set are reported as below detection levels, then all the data for that data set are assumed to be zero.

EPA also believes that a similar reasoning supports the use of the mid-point between the reported detection levels and reported quantification level. Under the proposal, States could always choose a more stringent approach as a general matter or in establishing individual TMDLs.

The proposed Guidance includes a definition of detection level that is identical to the definition long used by EPA, and published at 40 CFR 136.2(f). There is no similar long-established definition of the term quantification level. The proposed definition is the concentration at which a particular substance can be quantitatively measured. EPA solicits comment on whether this definition should be made more precise and, if so, how it should be changed. EPA is particularly interested in whether a particular degree of confidence should be specified.

A State's use of procedures for estimating representative background concentrations of pollutants shall be reviewed by EPA on a case-by-case basis when it approves or disapproves State

TMDLs submitted under section 303(d). The proposed requirements for determining representative background concentrations are based on the current practices of a majority of the Great Lakes States.

i. *General Condition 9.* General condition 9 establishes that nonpoint source load allocations must be based on existing or anticipated increased loading rates unless a lower loading rate is reasonably expected to occur within a reasonable period of time as a result of implementation of best management practices or other control measures. This general condition assures that nonpoint source contributions will be consistently considered as TMDLs are established and that anticipated reductions in loadings from nonpoint sources will be used in establishing TMDLs only where these reduced loadings are reasonably expected to occur.

j. *General Condition 10.* General condition 10 requires that if WLAs are expressed as a concentration of a pollutant in a discharge, that the TMDL also specify the point source effluent flow assumed in deriving the WLA. This will facilitate establishment of mass loading limitations in NPDES permits pursuant to the proposed Guidance. This general condition assures that common assumptions are used in establishing TMDLs and corresponding NPDES permit limits.

k. *General Condition 11.* General condition 11 establishes that once a TMDL is in place for a water body, a new source or new discharger can locate on the water body only if its loading is consistent with the existing TMDL (i.e., the TMDL included a reserved allocation for future growth) or the TMDL is revised to include an allocation for the new source. This general condition assures that the impacts of new sources will be considered.

5. Special Provisions for BCCs

Bioaccumulative chemicals of concern (BCCs) are those chemicals, which after considering metabolism and other physicochemical properties which might enhance or inhibit bioaccumulation, have a BAF of greater than 1000. Although levels of certain BCCs have significantly declined in recent years, the rate of decline has diminished and contaminant levels appear to be levelling off. It is estimated that under current loadings it will take years, perhaps decades, for fish tissue concentrations of certain BCCs to decline to levels that would allow unrestricted consumption of fish in the Great Lakes. Due to the unique characteristics of the Great Lakes, primarily long pollutant residence times, the Steering Committee wished to assure that similar problems did not occur in the future for other BCCs. A more detailed description of the rationale for the proposed increased controls on BCCs is provided in section I.D of this preamble.

a. *Reason for Restricting Discharge of BCCs.* The proposed Guidance would restrict the introduction and accumulation of BCCs in the Great Lakes System by requiring, in general, that mixing zones for existing discharges of BCCs be eliminated within 10 years and for new sources, that no mixing zone be provided. This proposed restriction reflects the Steering Committee's belief that every reasonable effort should be made to reduce all loadings of BCCs. In particular, the Steering Committee believed mixing zones should be eliminated for BCCs as a way to reduce mass loadings to the Great Lakes. The Steering Committee's approach is discussed further in section I.D of this preamble. EPA is seeking comment on whether the elimination of mixing zones over a 10-year period is an appropriate mechanism for addressing concerns with BCCs in the Great Lakes System.

b. *Elimination of Mixing Zones for BCCs.* Mixing zones are areas within the water body where the effluent mixes with the receiving water and where chronic water quality standards are not required to be met. Mixing zones for existing discharges of BCCs are proposed to be eliminated after a ten year period, after which time concentrations in any discharge which has the reasonable potential to cause or contribute to an excursion above a BCC criterion or value must be at or below the water quality criterion or value for the bioaccumulative pollutant. This ten year time period equates to two five-year terms for NPDES permits. This time period represents a reasonable period for implementing the phase out that works toward the Great Lakes Water Quality Agreement goal of virtual elimination of persistent toxic substances.

The concept of eliminating mixing zones for BCCs is consistent with current National regulations and guidance and the Great Lakes Water Quality Agreement. EPA regulations provide that States may, at their discretion, provide for mixing zones as part of their State water quality standards. The TSD recommends that States provide a definitive statement in their water quality standards as to whether or not mixing zones are allowed and states. As our understanding of pollutant impacts on ecological systems evolves, there may be cases identified where no mixing zone is appropriate. In addition, a general principle of the GLWQA at Annex 2 Paragraph 2.(d) supports the elimination of point source impact zones (mixing zones) for toxic substances.

c. *New Sources.* New sources of BCCs are not afforded the phase-in time. New sources that have a reasonable potential to cause or contribute to an excursion above a BCC criterion or value are to achieve the criterion/value at the discharge point at the time of commencing discharge.

d. *Mixing Zones During the Ten Year Phase Out.* Until mixing zones for existing sources of BCCs are phased out, TMDLs that include WLAs for such sources would be established using the mixing zone provisions set forth in each option or, where there are no specific provisions, in accordance with applicable requirements of State law.

e. *Exception to the Ten Year Phase Out of Mixing Zones.* Both options provide an exception to the required elimination of mixing zones (sections B.4 of both procedures 3A and 3B). Limited mixing zones may be granted beyond the 10-year period where water conservation measures leading to overall load reductions are used. When a facility implements water conservation measures, the concentration of the pollutant in the effluent may increase while the mass of the pollutants discharged does not. The Steering Committee believed that the effect of eliminating mixing zones could discourage permittees from utilizing water conservation measures, because of the potential for pollutants to increase in concentration in the effluent, causing a higher possibility that compliance with the concentration-based effluent limitation would not be achieved. The Steering Committee believed that because water conservation is desirable, that an exception may be appropriate in certain circumstances. The primary concern for BCCs is the mass of the pollutant entering the Great Lakes System. Concentration levels would still be controlled to assure no short term affects in the mixing zone. In no event, however, may the State grant mixing zones larger than those available when non-BCCs are discharged pollutants.

6. TMDLs for Open Waters of the Great Lakes

Both options describe the process for developing TMDLs for OWGLs, inland lakes and other waters of the Great Lakes System that exhibit lentic conditions (section 3.C of both procedures 3A and 3B). In both options,

general guidance for development of TMDLs on a lake-wide basis is provided.

a. *Point Source Mixing Zones for Chronic Criteria and Values.* Both options provide that absent a mixing zone study, individual wasteload allocations for point sources not be based on a mixing zone larger than is provided by mixing one part effluent mixed with ten parts lake water (containing background concentrations of pollutants). A smaller mixing zone or zero discharge may be deemed necessary to meet criteria and values.

The 10:1 mixing factor was derived from mixing zone studies conducted for the Milwaukee Metropolitan South Shore wastewater treatment plant and for the Green Bay Metropolitan wastewater treatment plant. For these cases, it was shown that the ten to one mixing factor represents an area of mixing where the velocity and momentum associated with an effluent being discharged from the end of a pipe is dissipated and any further dilution or mixing which then occurs is associated only with the typically slower natural process of diffusion, wind, temperature or current induced dispersion. The mixing zone assumption for open lake discharges accounts for background concentrations in the lake and essentially bases the TMDL on meeting criteria and values when one part effluent is mixed with ten parts lake water. Option A describes the 10:1 mixing zone in a narrative format, while Option B embodies the concept in a formula.

Under Option B, for non-BCCs, when a party believes that the 10:1 assumption does not reflect the actual area of discharge-induced mixing, a different mixing zone may be provided if the provisions of section 3.E of procedure 3B are met. Under Option A, the mixing zone available is not necessarily constrained by the area of discharge induced mixing if it is demonstrated that an alternative mixing zone is appropriate for protection of designated and existing uses and implementation of all criteria and values.

EPA invites comment on the relative merits of these different formats.

b. *Calculating Load Allocations.* Under both options, appropriate dilution assumptions to be used when establishing load allocations for nonpoint sources shall be determined in accordance with State law on a case-by-case basis by the authority establishing the TMDL.

c. *Protection from Acute Effects.* Option A provides for a cross check to ensure that acute criteria are met within applicable acute mixing zones authorized under State law. The option does not include a specific final acute value (FAV) cap, but instead relies on site-specific analysis of limits necessary to assure attainment of acute criteria and values within the applicable acute mixing zone.

To protect against acute effects in mixing zones, Option B requires that effluent limitations for point sources never exceed the final acute value (FAV). In some circumstances, however, the effluent limit may be required on a case-by-case basis to be more stringent than the FAV to protect against acute effects. The FAV is twice the CMC, as provided in the methodology for derivation of aquatic life criteria and values (appendix A to part 132).

d. *Procedures When High Background Concentrations are Present.* Under both Options, specific procedures are only provided for the situation where background concentrations do not exceed criteria or values. When ambient water quality concentrations do exceed chronic narrative or numeric criteria or Tier II values, any discharge that has a reasonable potential to cause or contribute to an excursion above a criterion or value should either be prohibited or a multiple source TMDL established that ensures the attainment of criteria or values. Under both Options, the procedures used in developing multiple source TMDLs for discharges to OWGL and other lentic waters are to be developed on a case-by-case basis, consistent with applicable regulatory requirements. There may be situations in which a phased TMDL is most appropriate. In a phased TMDL, best professional judgement is used to derive LAs and WLAs that will lead to attainment of water quality standards with a MOS. However, for example, due to large nonpoint source contributions and uncertainties regarding current loadings and probable success of nonpoint source controls, it is necessary to carefully monitor the effectiveness of the controls developed as a result of the TMDL. The phased TMDL and controls must result in attainment of water quality standards within a reasonable period of time, although during the implementation of controls, there will be a period of time when water quality standards may not be met. Frequent monitoring of the effectiveness of controls, particularly nonpoint source controls, is necessary in order to determine both the validity of the phased TMDL and the ultimate success of controls in attaining water quality standards.

Under the proposed procedure 9 of appendix F to part 132, compliance schedules in NPDES permits for point sources are limited to three years. Thus, there is a maximum period of eight years after the establishment of a TMDL in which permits can be reissued and point source limits consistent with a TMDL can be attained (five years for the expiration of existing permits and three years for the permittee to come into compliance with a new limit based on a TMDL). EPA also believes that in most situations it is appropriate to factor nonpoint sources reductions that are reasonably expected to occur within an 8 year time period into a TMDL, absent case-specific considerations.

e. *Margin of Safety*—i. *Chronic Criteria and Values.* In situations where background concentration do not exceed criteria and values, EPA believes that a MOS is generally provided through the use of a ten to one mixing zone. Given the size of the OWGL and other lentic receiving waters in the Great Lakes System, such a limited mixing zone provides a MOS with respect to attainment of water quality standards in ambient waters. In situations where a larger mixing zone is allowed based on a mixing zone study, the TMDL must include an explanation of how the MOS is provided.

ii. *Acute Criteria and Values.* EPA believes that restricting effluent levels to less than or equal to the FAV for acute criteria and values, provides the needed MOS. In other situations, such as TMDLs developed under Option A allowing larger loadings, the TMDL must include an explanation of how the MOS is provided.

7. TMDLs for Discharges to Tributaries

The principal differences between options A and B relate to TMDL development for tributaries. The initial focus of Option A is on attainment of water quality standards in a tributary basin, followed by assuring that water quality standards are attained at discharge points throughout the basin. Option A does not specify the size of mixing zones, leaving such considerations to existing State requirements. Option B, on the other hand, has detailed procedures for developing tributary basin and source specific TMDLs that are applicable where background concentrations do not exceed water quality standards. These detailed procedures include specific mixing zone provisions. Option B envisions development of tributary basin TMDLs at the discretion of the TMDL authority, or where the source specific procedures are not applicable or appropriate.

a. *Steady State Mass Balance Approach Common to Both Options.*

Both options envision predominant use of a simple, steady-state mass balance approach. A mass balance approach is a method used to approximate the mass of pollutants within a water body. It is based on the physical law of conservation of mass that states that mass cannot be created or destroyed but only transformed. This approach assumes that the input of mass into the system (e.g., through point and nonpoint source loadings, atmospheric deposition, groundwater seepage) equals the loss of mass from the system plus any losses due to transformation of mass within the system. Because both options assume a simple steady state, it is assumed that no mass can be accumulated in the system. This provides for a first approximation of allowable loading allocations. Subsequent monitoring will identify any shortcomings to this approach and indicate whether revisions are necessary. Although Options A and B are based on steady state conditions which assume fixed low flows, EPA is seeking comment on whether the final rule should allow the use of more sophisticated dynamic flow models.

b. *Design Flows Common to Both Options.* Many of the point source dischargers regulated under the Clean Water Act discharge effluent continuously to flowing streams. However, the amount of water available to dilute the discharge typically varies with the season and with periodic storm or drought conditions. In deriving TMDLs it is necessary to determine the stream conditions under which criteria and values must be attained. The criteria and values derived pursuant to today's Guidance are not designed to be never-exceeded values. Rather, they may be exceeded at varying frequencies and durations without injury to human health, wildlife or aquatic life.

Both options specify tributary design flows at which criteria and values are to be attained. The volume of water flowing through the tributary in a given time period at the design flow conditions is the volume that is considered available to dilute all pollutants present or introduced into the water body. Because of differences in criteria derivation methodologies, the proposed Guidance specifies different design flows for chronic aquatic life, wildlife, and human health criteria. For WLAs based upon chronic aquatic life criteria or values, the hydrologically-based 7Q10 flow or the biologically-based 4B3 flow is used; for TMDLs based upon wildlife criteria or values, the hydrologically-based 30Q5 flow is used; and for TMDLs based upon human health criteria, the harmonic mean flow is used.

With respect to implementing chronic aquatic life criteria using a mass balance approach, the proposed Guidance specifies the use of either the 7Q10 design flow or the 4B3 biologically-based design flow.

The 4B3 is that flow determined on a case-by-case basis that would provide for an excursion of chronic aquatic life criteria, over a 4-day averaging period, only once every three years. This flow is selected because criteria developed pursuant to procedures in the proposed Guidance may be exceeded over a 4-day averaging period once every three years without injury to the aquatic ecosystem. (See Technical Support Document to Water Quality-based Toxics Controls, or TSD)

The biologically-based 4B3 flow can be calculated by the computer program DFLOW supported on EPA's computers at the National Computer Center in Research Triangle Park, NC. (Further information may be obtained from Assessment and Watershed Protection Division, U.S. Environmental Protection Agency, 401 M St, S.W., Washington, D.C. 20460)

The second alternative design flow allowed in the proposed rule is the hydrologically-based 7Q10 flow. The 7Q10 is the lowest 7-day average flow expected to occur on the average once in every ten years, based on the period of record. Empirical data from approximately 60 streams show that the 7Q10 flow provides a degree of protection approximately equivalent to the 4B3 flow. Statistics based on stream gages operated by the U.S. Geological Survey are routinely published. These statistics commonly include estimates of the 7Q10 for most riverine systems.

EPA solicits comment on whether the final rule should specify a design flow for the purposes of implementing acute aquatic life criteria. Current EPA guidance recommends use of a 1Q10 for this purpose (Technical Support Document for Water Quality-based Toxics Control). The design flow would be used in conducting acute cross-checks under Option A, and in determining whether the FAV cap is sufficient to protect against acute effects in Option B.

Human health criteria represent ambient pollutant concentrations that are acceptable based on a lifetime (70 years) of exposure. Accordingly, discharges should be regulated such that criteria will not be exceeded under stream conditions that represent long-term average conditions. Current EPA guidance recommends use of the long-term harmonic mean flow to implement human health criteria (TSD). The harmonic mean flow is the sum of the reciprocals of individual flow measurements divided into the total number of individual flow measurements.

Since wildlife criteria have not been implemented by EPA before, there is no current EPA guidance regarding a design flow for their implementation. Based on the recommendations of the State of Wisconsin and the GLWQI Steering Committee, EPA is proposing that a 30Q5 flow rate be used for the implementation of wildlife criteria. This is the lowest 30-day average flow that would occur on the average every five years based on a statistical review of historic flow data.

The Steering Committee's starting point in selecting a 30Q5 flow rate for wildlife criteria was analysis of the 7Q10 flow rate currently used in the implementation of aquatic life criteria. For wildlife, impacts of chemicals with a high propensity to bioaccumulate in aquatic organisms is of greatest concern. Aquatic organisms comprise a major portion of the diet of many wildlife species. Because of relatively slow rates of uptake by aquatic organisms of bioaccumulative chemicals, residues in the food chain would have a delayed response to increases in ambient concentrations of chemicals during short-term periods, such as during low flow events. Accordingly, the Steering Committee judged a 30-day averaging period was more appropriate than the 7-day averaging period used in the aquatic life design flow. The Steering Committee selected a five-year return interval as adequate to ensure that criteria exceedances did not occur too frequently to interfere with reproduction of wildlife species, and no unacceptable adverse effects on the population would result.

EPA recognizes that the use of a 30-day averaging period is conservative given the long time it may take for bioaccumulative chemicals to reach steady state in an aquatic organism. EPA is interested in receiving comments on the proposed 30Q5 design flow for the implementation of wildlife criteria. Given the long time to equilibrium for bioaccumulative chemicals, EPA particularly solicits comments on whether a 90Q10 flow, the long-term (period of record) harmonic mean flow, or the lowest annual harmonic mean flow expected to occur on the average within a 5 or 10 year period should be used for the implementation of wildlife criteria. The latter two alternatives above are essentially a 365Q5 or 365Q10, where a harmonic mean rather than an arithmetic mean is used.

Comments are requested on these flow rates because the harmonic mean is recognized as a better predictor of the average concentration than is the arithmetic mean.

The requirements in the proposed Guidance for use of design flow are consistent with the recommendations in the TSD. A more complete description of the selection of design flows, steady-state and dynamic modeling approaches, and the reasons for the requirements in today's proposed rule may be found on pages 36, 78–82, and appendix D of that document. EPA invites comment on the use of these design flows and on the use of steady-state and dynamic modeling approaches.

c. *Overview of Option A—i. Load Inventory.* A load inventory is prepared under Option A that documents all loadings from point and nonpoint sources to the entire basin. Option A allows a number of different data sources to be used in calculating loadings from point sources: Current NPDES permit limits, calculated limits reflecting new technology-based requirements, interim limits in an enforceable schedule of compliance, and actual loadings of pollutants determined, for example, through discharge monitoring. The data source actually used in a load inventory should be determined on a case-by-case basis, with the objective of ensuring the ultimate success of the TMDL in bringing about attainment of water quality standards.

The load inventory also includes natural background loadings of pollutants, and loadings from nonpoint sources. It may be particularly difficult to assess loadings from nonpoint sources. Any uncertainties in this regard should be reflected in the margin of safety established for the TMDL.

Pollutants may degrade into non-toxic byproducts as they travel from the point of discharge to the farthest downstream location in the tributary basin. It is permissible to discount pollutant loadings to the farthest downstream point of the basin to the extent that degradation can be estimated with accuracy.

ii. *Loading Capacity.* The next step in deriving a tributary TMDL under Option A is to calculate the total loading of pollutants that can enter the basin and still ensure attainment of all applicable water quality standards at the furthest downstream location in the basin. When chronic numeric criteria or values are available, this loading capacity is calculated by multiplying the numeric criterion or value, expressed as a concentration of pollutant, times a given tributary design flow. As is discussed above, the design flow varies with the type of criterion or value being implemented. For example, the loading capacity associated with attaining chronic aquatic life criteria is calculated for a design flow representing the lowest 7-day average flow that occurs once every 10 years. The loading capacity associated with implementing human health criteria or values, on the other hand, is calculated based on the harmonic mean flow of the stream. Thus, for example, if a human health criterion is expressed as 10 milligrams of pollutant per liter of water, and 10 million liters of water pass the lowest downstream location of the tributary during a day at the harmonic mean flow, then the loading capacity of the tributary would be 100 kilograms of pollutant per day.

Where numeric criteria or values have not been calculated, a case-by-case determination must be made as to the loadings of pollutants to the tributary that are consistent with attainment of narrative water quality criteria and protection of designated and existing uses.

If degradation is assumed in calculating the baseline inventory, it should also be assumed in calculating the loading capacity of the tributary basin. This may be difficult, however, since the loading capacity will vary depending on where the pollutants are introduced. Correlation to existing loading patterns will ensure the most accurate estimate of loading capacity given the current discharge situation.

iii. *Basin Margin of Safety.* TMDLs are to be derived with a margin of safety to account for uncertainties. An assessment of uncertainties in calculating the loading inventory and loading capacity should be made, and a portion of the basin loading capacity set aside as a margin of safety that reflects the uncertainties presented. Of course, if the loading inventory and loading capacity are initially calculated in a conservative (protective of the environment) manner, then a separate set-aside of loading capacity for a margin of safety may not be necessary.

iv. *Load Reduction Targets.* The loading capacity minus any specified basin margin of safety is the loading that is available for allocating to all sources (including natural background) of the basin. The amount of load reduction necessary to meet water quality standards at the downstream end of the tributary can be calculated as the baseline inventory load minus the basin loading capacity adjusted by any specified basin margin of safety.

v. *Basin Allocations.* Allocations are made consistent with load reduction targets identified above. TMDLs must not include allocations which are not reasonably anticipated to be attained. Accordingly, load allocations for nonpoint sources should be based on current or anticipated increased loadings, unless there is a reasonable basis for assuming that there will be a reduction in nonpoint source loadings within a reasonable time period. As discussed above, EPA will typically consider eight years to be a reasonable time period. Whatever portion of the loading capacity is not allocated to nonpoint sources, background, and reserve capacity for future growth may be allocated to existing point source dischargers.

vi. *Site-specific Cross-checks.* After allocations are established to ensure attainment of water quality standards at the furthest downstream location in the tributary, site-specific cross-checks are conducted at each source location to ensure that water quality standards (acute and chronic aquatic life, wildlife and human health) are attained at the edges of applicable mixing zones or, if mixing zones are not allowed under state law, throughout the basin. Option A does not specify the size of mixing zones for this purpose; mixing zone requirements (if any) adopted by the various states will be used for the cross-checks. The cross-checks should apply the margin of safety concept to the local discharge area. In addition, they must account for background concentrations of pollutants in the immediate vicinity of the discharge.

If a site-specific cross-check indicates that standards will not be attained in the vicinity of a nonpoint source, the LA may be reduced if such a revised LA can reasonably be expected to be promptly attained by that source in a reasonable time period. Otherwise, WLAs for upstream point sources must be reduced to ensure attainment of standards in the vicinity of the nonpoint sources. In some instances it may be more economical for the upstream point sources to fund nonpoint source control measures to achieve needed load reductions than to institute additional treatment measures at their locations. If such an agreement is binding on the parties and can reasonably be expected to promptly provide the needed load reductions in a reasonable time period, the TMDL can include a reduced load allocation reflecting the agreement.

vii. *Establish Final Allocations.* Final allocations in TMDLs developed under Option A are the more stringent of those developed through the basin analysis or through site-specific cross checks.

However, if certain basin allocations are reduced as a result of site-specific cross checks, other basin allocations could be correspondingly increased provided that such increased allocations are deemed acceptable after conducting site-specific cross-checks.

viii. *Monitoring Provisions.* If there is a significant nonpoint source contribution of the pollutant addressed in the TMDL, the TMDL should typically include a monitoring plan that will test the success of the TMDL in leading to attainment of water quality standards. States may consider performing the monitoring themselves, or requiring ambient monitoring as a condition of NPDES permits issued to point source dischargers of the pollutant. If the ambient monitoring indicates continued exceedances of water quality standards, the TMDL should be revised to include more stringent allocations. Such phased TMDLs are appropriate when nonpoint sources are present because it is currently very difficult to accurately estimate nonpoint source loadings and reductions that can be achieved through implementation of nonpoint source controls.

d. *Overview of Option B.* Option B includes detailed procedures to derive tributary basin and source specific WLAs for point sources where background concentrations do not exceed water quality standards, but where the additional discharge of the point source or sources in question has a reasonable potential to cause or contribute to such an exceedance.

The detailed source specific procedures could pose an inequitable burden in some situations on the particular point source responsible for the marginal loading that could result in a water quality standards exceedance. Upstream sources also contributing to the water quality impairment would not need source-specific TMDLs under this approach. Accordingly, Option B also includes an approach for deriving tributary basin TMDLs that would spread the load reduction burden among a number of sources. A tributary basin TMDL is also necessary where background loadings at point source locations exceed applicable water quality standards.

Consistent with the general conditions set forth in section A.2 of procedure 3B, the tributary basin TMDL will include WLAs for point sources and LAs for nonpoint sources such that their sum is not greater than the loading capacity minus the sum of any specified MOS and reserve capacity for future growth. Also, each individual WLA must be no less stringent than the requirements for source specific TMDLs as specified in section D.3 of procedure 3B.

i. *Source-specific TMDLs.* Option B includes a formula in section D.3.c.i of procedure 3B for deriving a WLA in situations where background concentrations do not exceed water quality standards. By considering background concentrations in the formula, all upstream loadings are accounted for, and a WLA is generated that will ensure attainment of water quality standards at the discharge location. The proposed formula reflects current EPA guidance for deriving a WLA using steady state mass-balance assumptions:

$$WLA \le \frac{(\text{criterion})[Q_{ad} + (1-f)(\text{effluent flow})] - (\text{background})Q_{ad}}{\text{effluent flow}} \quad (X)$$

The formula contains five major functional components. The first component of the formula is the WLA—the mass of pollutant that may be discharged over a given period of time by the point source and still provide for attainment of water quality standards. The second major component of the formula is:

$$(\text{criterion})[Q_{ad} + (1-f)(\text{effluent flow})]$$

This set of terms calculates the mixing zone capacity (expressed as mass of pollutants per unit of time) within a specified mixing zone and accounting for water introduced by the point source to the stream. The third major component of the formula is (background)Q_{ad}. This component calculates the loading (also expressed as mass of pollutants per unit of time) already present in the volume of stream flowing to the discharge location that will be used for mixing. The mixing zone capacity minus the background loading yields the additional point source loading (in mass per unit of time) that may be discharged without causing an exceedance of water quality standards. When this is divided by the effluent flow in units of volume per unit time, the fourth major component of the formula, it yields a concentration that may be discharged (in units of mass per volume of flow). The fifth factor in the equation, X, is used to convert the concentration based value to a mass based discharge limitation expressed over an appropriate time period (such as mass discharge per day). The loading capacity and background loading components of the formula are described in more detail below.

ii. *Mixing Zone Capacity.* The mixing zone capacity is the capacity to assimilate pollutants and attain criteria in the portion of the stream designated for mixing, assuming no pollutants present, and is provided by:

$$(\text{criterion})[Q_{ad} + (1-f)(\text{effluent flow})]$$

The criterion is a chronic Tier I criterion, chronic Tier II value, or other numeric criterion or numeric interpretation of a narrative criterion, expressed as a concentration of the pollutant. A chronic criterion or value is

designed to protect against effects that may arise due to long-term exposure. Such criteria are typically more stringent than acute criteria, so this implementation typically also provides protection from acute or subchronic effects, depending upon mixing zone considerations.

The Q_{sd} is that portion of the receiving water at an appropriate design flow that is allowed to be used to dilute the discharge. Section D.3.c.ii of procedure 3B specifies that the Q_{sd} is calculated by multiplying the stream design flow by the dilution fraction. As discussed in more detail above, the design flow of the stream varies with the type of criteria being implemented (e.g., chronic aquatic life or human health), and accounts for the fact that there typically will be differing amounts of dilution water available in a stream depending on the season and periods of drought or flooding. WLAs for continuous discharges must consider this variability in receiving water flow.

The dilution fraction is derived based on the relationship of the effluent flow of the point source to the flow of the receiving water, and an assumption regarding how rapidly mixing occurs. Stream data showing effluent and receiving water flow show that the discharge from a point source to a small stream will mix relatively rapidly with a greater percentage of the water in the receiving stream as compared to the discharge of a similar point source to a large stream. The ratio of the stream flow to the effluent flow is used in section D.3.c.iii of procedure 3B to determine the amount of flow to be granted as the default dilution fraction. The dilution fraction varies from 0.1 to 0.25, depending on this ratio. Thus, the dilution fraction specifies the size of the mixing zone in terms of the percentage of stream flow (10–25 percent) that is available for dilution. The proposed Guidance provides for an opportunity to demonstrate that a larger mixing zone is acceptable within the constraints set forth in section E. In no case, however, may the dilution fraction exceed 0.75.

The concept of the fraction of the stream design flow is based upon recommendations found in the Water Quality Criteria—Report of the National Technical Advisory Committee to the Secretary of the Interior, April, 1968 (Green Book) and upon guidance from EPA's 1983 Water Quality Standards Handbook. The Green Book recommended that in order to prevent the initial mixing of wastewater of point sources from erecting a barrier to fish and other aquatic organisms, only 25 percent of the cross-sectional area of the river should be used for mixing. The Handbook suggests that the value of 25 percent of total river flow is a rational estimate of the amount of river flow in 25 percent of the cross-sectional area. The basis of the use of a fraction of the cross-sectional area is then tied to the allowance for mixing zones found in each State's water quality standards. The use of the 25 percent fraction has been incorporated as policy in the water quality standards of some States across the Nation and included in the Great Lakes System for many years in order to account for the uncertainties surrounding available data, discharge fluctuations, impacts on aquatic resources, etc. Option B's use of a fraction of the cross-sectional area for deriving WLAs is consistent with the longstanding EPA guidance and State policies on mixing.

The proposed procedure specifically sets the default dilution fraction to vary inversely with the stream flow to effluent flow ratio. A larger portion of the stream design flow is allowed for those situations where the source flow closely approximates the stream design flow. This means that when the effluent mixes with the stream rapidly, a larger portion (25 percent) of the stream is justified as a dilution fraction. But when the effluent does not mix rapidly with the stream, a smaller portion (10 percent) of the stream flow is justified as a dilution fraction. This reduction in the dilution fraction effectively reduces the volume of water available for dilution in larger rivers. This reflects a compromise approach when compared to some States within the Great Lakes System. For example, the State of Ohio uses a graduated scale for the fraction that ranges between 10 percent and 100 percent of the stream design flow. The State of Michigan, on the other hand, uses a straight 25 percent of the stream design flow for all categories of criteria or values, with an opportunity to demonstrate for a larger percentage.

Similar to the approach used by Ohio, the dilution fraction is only determined based upon the ratio of the 7Q10 to the effluent source flow. Once a dilution fraction is determined, the same dilution fraction would be used when assessing the need for all water quality-based controls for a particular discharger. As required by the proposed Guidance, the dilution fraction would never be determined using the harmonic mean 30Q5 flow of a receiving water. The constant dilution fraction for varying stream design flows is specified in order to ease administrative burden. EPA solicits comments on the proposed method of calculating a default dilution fraction, and also solicits suggestions (with supporting rationale) for alternative methods.

EPA believes that the dilution fraction provisions are conservative, and contribute to a margin of safety for TMDLs derived using the equations. As such, EPA believes that in most situations an additional margin of safety will not need to be provided when this equation is used to derive source-specific TMDLs. This procedure, however, may not provide an adequate MOS where there is more than one discharger in a relatively short stretch of river where the design flow (drought flow) of the receiving stream does not substantially increase between the upstream and downstream dischargers or where background levels are high. In such a situation, the tributary basin procedure should be used, or some other method used to provide an adequate margin of safety.

The approach is somewhat more conservative (contributes more to a MOS) with respect to TMDLs for wildlife and human health criteria, since the dilution fraction is always calculated using the low design flow (7Q10) used to implement chronic aquatic life criteria. EPA believes that use of the formula will promote consistency in developing TMDLs in the Great Lakes System. Comments on the proposed mixing zone/margin of safety approach built into the formula are specifically invited.

The component of the formula that is used to calculate loading capacity also includes the terms (1-f)(effluent flow). "f" is defined as the fraction of the effluent flow that is withdrawn from the receiving water.

The (1-f) factor is applied to take into account whether or not the point source is increasing stream flow (and available dilution) by adding water to the receiving stream. In situations when the receiving water of the discharge is the same water body as the facility's source water, the flow from the effluent should already be accounted for in the stream flow value and the receiving water is only receiving additional loading of pollutants. Where the facility source water is from a different water body than the receiving water, the factor has the effect of increasing the allowable dilution flow of the stream to account for the additional water introduced by the point source.

iii. *Background Loadings.* The background conditions of the receiving water are accounted for in the formula in proposed section D.3.c.i of procedure 3B by the term (background) Q_{sd}. As discussed above, Q_{sd} is the portion of the receiving water that is allowed to dilute the discharge. When this flow is

multiplied by the background concentration of pollutants in the receiving water immediately upstream of the point source (calculated in accordance with section A.8), the result is a background loading of pollutants in the portion of the receiving water flow that is available for diluting the discharge, in units of mass of pollutants per unit of time.

iv. *Formula Modification Based on Mixing Zone Studies.* Option B allows any interested party to prepare a mixing zone study and allows the TMDL authority to modify the dilution fraction described above in accordance with such studies. The dilution fraction could be either reduced or eliminated, or increased to a maximum of 75 percent of the 7Q10 flow. Option B, section E describes several required elements of a mixing zone study, all designed to address the area of mixing that can be allowed consistent with attainment of water quality standards. Mixing zone studies are to assume that pollutants do not degrade within mixing zones, unless the mixing zone study is accompanied by scientifically valid field studies or other relevant information demonstrating that degradation of the pollutant will occur in the mixing zone under the full range of environmental conditions expected to be encountered and such studies or other information also address factors other than degradation that affect the level of pollutants in the water column, including resuspension of sediments, chemical speciation, and biological and chemical transformation.

v. *Limitation on Use of Source-specific TMDL Formula.* In situations where the term (background) Q_{bd} is larger than the term (criterion)[Q_{bd} + (1-f)(effluent flow)], the formula will generate a negative WLA. This will typically occur where the background concentration of pollutants exceeds criteria levels, and the point source uses the receiving water as its source of intake water. Where the formula generates a negative WLA, a discharge which has the reasonable potential to cause or contribute to an excursion above a criterion or value cannot be allowed unless a multiple-source TMDL is prepared that will ensure attainment of water quality standards.

e. *Pollutant Degradation.* Although pollutant degradation may be considered for different purposes under Options A and B, both Options allow TMDLs to account for degradation of a pollutant provided two conditions are met. The first condition is that the regulatory authority must have information regarding the rate of degradation of the pollutant in the form of field studies or other relevant information. Field studies, if used, must document that degradation of the pollutant will occur under the full range of critical conditions expected to be encountered, and should quantify the degradation. Critical conditions should include the design conditions that are established for the implementation of criteria in ambient waters as well as other conditions such as periods of stratification of the water body and variability of the facility effluent flow rate. If field study information is not available, the regulatory authority can use other relevant information such as literature references from similar sites. Regardless of the type of information used, all information must be reviewed by the regulatory authority and found to be scientifically valid. EPA invites specific comment on what type of information is sufficient to demonstrate degradation in ambient waters, and in particular, whether literature information or field data from similar sites can be used to quantify degradation.

The second condition is that the studies take into account factors other than pollutant degradation that affect the concentration of the pollutant in the water column including but not limited to resuspension of sediments, speciation and transformation.

The Steering Committee recommended including a requirement that the degradation in the mixing zone must be rapid and significant. EPA is not proposing these requirements today since these terms are vague and since any degradation that does occur in the mixing zone will in practice be rapid due to the relatively small size of the mixing zones. Further, EPA does not believe that the degradation need be significant, but rather that the permittee be allowed to receive consideration for any degradation that can be demonstrated to occur in the mixing zone.

The Steering Committee recommended that the Guidance specify that losses from the water column due to physical transfer of pollutants to other media is not an acceptable environmental fate process for increasing TMDL allocations. The Steering Committee was concerned that inter-media transfers, including volatilization (evaporation from the water to the atmosphere), bioaccumulation in the tissues of organisms and sorption to sediment and suspended solids in the water body may not be permanent losses and that pollutants could be reintroduced into the water column at some later time. EPA is not proposing these requirements today, however, because EPA believes that the concerns of the Steering Committee can be answered through other mechanisms.

Each of the Great Lakes States has already adopted a narrative criterion specifying that waters shall be free from pollutants that settle to form objectionable deposits. EPA's existing NPDES requirements (40 CFR 122.44(d)) require permit effluent limitations to meet these narrative criteria. Each option also contains identical text in general condition 6 requiring that TMDLs prevent the accumulation of pollutants in sediments to levels injurious to designated or existing uses. Inclusion of this provision in the proposed Guidance reflects EPA's concern about sediment quality in the Great Lakes System and a recognition that it may often need to be considered.

EPA is currently developing new methods for preventing sediment contamination. The first step is to develop numeric sediment criteria guidance. Upon State adoption of sediment criteria as part of a State WQS, regulatory authorities will need to factor such criteria into the TMDL and NPDES permitting process.

To the extent that volatilization does not represent a permanent loss from the Great Lakes System, it will be accounted for in determining background concentrations. Accordingly, it does not seem necessary to prohibit accounting for volatilization in establishing TMDLs. It would be extremely difficult to establish a significant loss of ambient pollutants as a result of bioaccumulation. Since most TMDLs assume steady state conditions, it should also be assumed that the aquatic biota is at equilibrium regarding pollutant uptake and depuration.

Likewise, the potential loss of pollutants from the water column by bioaccumulation into fish tissue is offset by the return of pollutants via depuration in more complete models. Again, the regulatory authority has available a more appropriate mechanism for addressing physical transport. Finally, EPA believes that pollutant volatilization is an irreversible loss of pollutants from water column. EPA recognizes that allowing discharge of volatile pollutants may lead to elevated pollutant concentrations in the air. However, EPA believes that these potential releases are better controlled using other statutory authorities, for example, the Clean Air Act. EPA invites comment on whether some or all physical transport processes should be precluded from consideration in the development of TMDLs and WLAs.

8. Pollution Trading Opportunities

The TMDL process provides an opportunity for pollution trading in the water quality program as long as CWA goals and requirements are met. Effluent limits and nonpoint source controls, for example, must be designed, maintained and enforced so that water quality standards and other program requirements are met. For purposes of the proposed Guidance, trading refers to approaches which introduce market incentives into water quality control decisions by acknowledging the ability of a point source to achieve water quality based loading reductions through creative, enforceable, market mechanisms.

The proposed Guidance allows States to look for pollution trading opportunities as TMDLs are established. It should be noted, however, that some of the general conditions of applicability in both Options may limit trading opportunities since they specify, for example, that mixing zones for BCC discharges must be eliminated within 10 years and focus primarily on developing TMDLs necessary to derive point source permit limits. These types of conditions may serve to define the characteristics of trading programs acceptable within any given basin of the Great Lakes System.

While the proposed Guidance focuses primarily on providing two options designed to provide consistent TMDL procedures among the States, each option does provide general guidance for completing TMDLs on varying geographic scales. TMDLs completed for larger geographic areas are generally more complex and deal with pollution from point and nonpoint sources. As the number of sources and pollutants included in a TMDL and the geographic area grows larger, opportunities for trading and the types of trading programs appropriate to specific sites and water quality problems will grow.

9. State Adoption

In order to achieve consistent application of the TMDL procedures, the proposed Guidance would require States to adopt a TMDL procedure consistent with procedure 3 of the final Guidance, or an equally stringent alternative. If a State chooses to adopt an alternative approach, the selected approach must result in equal or more stringent controls than the final procedure 3.

10. Summary of Other Options Considered

Earlier drafts of procedure 3 focused only on the development of WLAs for point sources using predominantly Option B. One State, New York, uses a different TMDL procedure from the other Great Lakes States. During the Technical Work Group sessions it became evident that these approaches differed in respect to establishing TMDLs for tributaries and in the general level of detail and assumptions used. The Steering Committee, believing that both approaches may be consistent with National guidance and the GLWQA, decided to propose both approaches as options and to request comment on them.

Additionally, the Steering Committee considered whether, based upon demonstrations that the effluent rapidly mixes with the receiving water, the regulatory authorities should have the flexibility to specify effluent limitations based upon acute aquatic life criteria which are greater than the FAV. These demonstrations would define the acute mixing zones, which are also known as zones of initial dilutions (ZIDs) and areas of initial mixing (AIMs). As explained earlier in the preamble, Option B restricts the WLA for the control of acute toxicity to not greater than the FAV, while Option A provides for case-by-case determinations and applications of State-developed acute mixing zone policies in deriving WLAs necessary to prevent acute toxicity. EPA would like to receive comments on the relative merits of the two approaches.

The Technical Work Group had recommended that Option B prohibit mixing zones from extending from a tributary into a lake or connecting channel. The prohibition was intended to ensure that additional mixing based upon the dilution from OWGLs or CCGLs would not be incorporated into the WLA development. EPA was concerned that this prohibition could result in an inequitable elimination of mixing zones for sources located at the mouths of tributaries. Accordingly, this language was deleted from the proposed Guidance and replaced with a condition in section D.2 of procedure 3B requiring that when information on mixing zones is available for a point source discharge that demonstrates that the mixing zone extends into an OWGL or CCGL, the WLA is determined using the more stringent dilution allowance provided in either section C.1 or section D.3.c. States will use professional judgement in assessing when a mixing zone extends beyond the boundary of the tributary basin. EPA solicits comments on whether this revision to the recommendation of the Technical Work Group is appropriate and, if not, alternative proposals for dealing with discharges at the mouth of tributaries.

11. Request for Comments

Comments are invited on all aspects of the two proposals for TMDL development and on possible alternatives. EPA is interested in receiving comments individually on both Options A and B. Areas in which EPA is particularly interested in receiving comments include the overall technical and programmatic approach set out in each option, the technical issues involved in applying each option to a varied set of water quality problems, consistency with existing national policy and program approaches and the degree to which each option allows for integrated development of effective point and nonpoint source controls. In addition to comments on each option, EPA is also interested in receiving comments on the consistency between Options A and B. EPA is particularly interested in receiving comments concerning the overall compatibility, technical and programmatic strengths and weaknesses of each option. EPA is particularly interested in the potential impact that any differences in these options might have on the perceptions and interest of the public and regulated community.

Comments are also invited on how the options should be incorporated into the final implementation procedures. EPA is very interested in receiving comments which address the compatibility of these two options. Should, for example, all the States in the Great Lakes System be required to adopt either Option A or B, or a combined approach so that only one consistent approach is employed throughout the Great Lakes System. Or, alternatively, should States be required to adopt one or the other of these options so that all the States in the Great Lakes basin are committed to using either Option A or B. Finally, should States be permitted to use one or the other option according to the situation at hand. EPA also solicits comments on the option of not providing specific TMDL provisions in the final Great Lakes Guidance, relying instead on a continuation of the existing national program in this area.

EPA would like to receive comments on the elimination of mixing zones for BCCs. In addition, EPA welcomes comments on whether the 10-year implementation period is reasonable and if other periods are more appropriate.

EPA would also like comments from the public on whether acute mixing zones should be allowed and if so, whether the Guidance should include any maximum size for acute mixing zones, and what that size should be.

Further, EPA would like comments on the need for, and applicability of, a final effluent cap, such as the Final Acute Value which is proposed in Option B.

EPA invites comment on the procedures to account for the environmental fate of pollutants, including: the requirement for the permittee to submit documentation on the rate of degradation inside the mixing zone; allowing field studies based on a similar stream and a similar discharge to be considered acceptable and the information to be submitted by the permittee.

EPA also invites comments on the provisions related to background data requirements, specifically on how background is defined and on including caged fish tissue and loading data as acceptable available data. EPA also invites comment on the requirement that the background concentrations be representative and on providing relatively little detail in the methodology regarding determination of what is representative, or on how to adjust data to make it representative.

The public is also invited to comment on setting data points below the detection level to one-half of the reported detection level for the purposes of calculating a geometric mean; setting data points between the detection level and the quantification level at the mid-point between the two reported levels; and setting the background level as zero when all data are below the level of detection.

It is EPA's intent that the Great Lakes States will, at a minimum, use this procedure for developing TMDLs for all pollutants except those identified in Table 5 of the proposed Guidance. The results of dynamic modeling may be used only where the results can be shown to be more restrictive than the results due to the steady-state assumptions of both options in proposed procedure 3. EPA would like comments on whether the States should be allowed to use the results of dynamic modeling whether the results are less stringent or not when compared with the results using the steady-state approaches in procedure 3.

Finally, commenters may provide additional information or alternative approaches to TMDL development. In particular, EPA welcomes comments on means for controlling nonpoint sources.

D. Additivity

1. Introduction

Traditionally, EPA has developed numerical criteria on a single pollutant basis. However, many instances of contamination in surface waters involve mixtures of two or more pollutants. Such mixtures can interact in various ways which may affect the magnitude and nature of risks or effects on human health, aquatic life and wildlife. With respect to impacts on aquatic life, the interactive effects of discharged pollutants on organisms is ascertained through direct exposure of test organisms to a point source effluent in whole effluent toxicity (WET) tests as described in procedure 6 of appendix F of the proposed Guidance. The use of such tests to determine additive pollutant effects on aquatic organisms is a well-established component of existing Clean Water Act regulatory programs. EPA currently has no guidance regarding consideration of additive effects of pollutants on wildlife.

EPA has considered mechanisms for assessing effects resulting from human exposure to pollutant mixtures. On September 24, 1986, the EPA published "Guidelines for the Health Risk Assessment of Chemical Mixtures (51 FR 34014)," which is available in the administrative record for this rulemaking. These guidelines set forth principles and procedures for human health risk assessment of chemical mixtures. Although the calculation procedures in these guidelines differ for carcinogenic and non-carcinogenic effects, both procedures assume dose additivity in the absence of information on specific mixtures. Dose additivity is based on the assumption that the components in a mixture have the same mode of action and elicit the same types of effects. Because information on the interaction of pollutants and on the modes of action is so sparse, EPA recommends in the 1986 guidelines that risk assessments of mixtures be based on an assumption of additivity, as long as the components elicit similar effects. Dose additivity could result in errors in risk estimates if synergistic or antagonistic interactions occur (i.e., additivity assumptions could result in overestimates or underestimates of the actual risks). Thus, the assumption is not a "worst-case" assumption, but a reasonable assumption within the bounds of possibility when specific information on pollutant interaction is not available.

In an effort to address the concurrent human exposure to combinations of carcinogens, three Great Lakes States (Illinois, Minnesota and Wisconsin) assume in criteria development that the risk of a combination of carcinogens in a mixture is equal to the sum of risks associated with exposure to each individual pollutant in the mixture. These three States have adopted an acceptable cancer risk level of 10^{-5} for exposures to individual pollutants. In Minnesota and Wisconsin, the total risks associated with exposure to mixtures is not to exceed 10^{-5} while Illinois allows a total cancer risk level of 10^{-4} for exposure to mixtures.

The Great Lakes Water Quality Agreement addresses this issue in Annex 12, which states that "The Parties shall establish action levels to protect human health based on multimedia exposure and the interactive effect of toxic substances." In addition, Annex 12 of the Agreement recommends that research efforts on the interactive effects of residues of toxic substances on aquatic life, wildlife, and human health be intensified. A supplement to Annex 1 of the Agreement also provides for the development of specific objectives addressing synergistic and additive effects of pollutants.

2. Approaches Considered

The Committees of the Initiative sought to develop a consistent approach to additivity within the Great Lakes States. Their deliberations resulted in proposals for the use of additivity for the protection of aquatic life, wildlife and human health. EPA evaluated the Committees' proposals as well as other alternatives; both the Committees' proposals and alternatives are discussed below.

EPA's traditional approach is to address each pollutant on an individual basis in the derivation of criteria and values. However, EPA has provided guidance in the past on how to take additivity into account for the protection of aquatic life and human health. With respect to the proposed Great Lakes Water Quality Guidance, EPA invites comment on the additivity-related issues discussed below and on whether a specific procedure, should be either required or set forth as guidance in the final rule.

a. *Aquatic Life.* As proposed by the Committees of the Initiative, the proposed Guidance accounts for additive effects on aquatic life through establishment of whole-effluent toxicity (WET) limitations. WET requirements are proposed under procedure 6 of appendix F of the proposed Guidance.

b. *Human Health—Carcinogens.* For carcinogenic effects on human health, the 1986 guidelines for mixture recommend that in the absence of contrary information it be assumed that the total cancer risk posed by a mixture of chemicals is the sum of risks posed by exposures to individual chemicals. Since information on the interaction of pollutants in a mixture is generally

rather limited, the 1986 guidelines recommend the use of the additivity assumption under most circumstances. However, the guidelines indicate a preference for relying on actual data on the interaction of pollutants in mixtures whenever adequate data are available. Therefore, EPA recommends that in those cases where it can be demonstrated that the carcinogenic risks of a mixture are not additive, the additivity assumption should not be used.

In its December 16, 1992, report, "Evaluation of the Guidance for the Great Lakes Water Quality Initiative," the EPA's Science Advisory Board (SAB) stated that additivity should not be used as a default, but rather multiple carcinogens should be considered on a case-by-case basis. This is because additivity assumes a common mechanism of action and carcinogens are known to act by a wide variety of mechanisms and to target different organs. The SAB report goes on to say that for compounds that act at the same receptor (such as dioxin, furans and PCBs) an assumption of additivity might well be defensible. EPA invites comment on whether the assumption of additivity for carcinogens should be limited to those situations when adequate data are available on the mechanisms of action.

EPA invites comment on whether the narrative criteria of the States and Tribes providing that waters be free from substances that injure or are toxic to humans, animals or plants should be interpreted to account for the additive effects of chemicals. The purpose of this approach would be to prevent the total risk associated with carcinogens in ambient waters from exceeding a non-appreciable level. As discussed elsewhere in the proposed Guidance, EPA is proposing criteria/values for single pollutants based on a 10^{-5} cancer risk level. EPA believes that the use of a risk level on total risk associated with chemical mixtures would enhance protection of human health, and consistency in addressing additive impacts throughout the Great Lakes System. It would also be consistent with the provisions of the Great Lakes Water Quality Agreement calling for consideration of the interactive effects of toxic substances. Insofar as it may require greater reductions of pollutant discharges than would be required through implementation of individual chemical criteria alone, it would also further the "virtual elimination" goal of the Agreement. EPA requests comments on the possible use of 10^{-5} as a cap on the cancer risk associated with mixtures and on alternative risk levels (e.g., 10^{-4}) that may be considered. A specific option that would require interpretation of narrative criteria to establish a 10^{-5} cap on cancer risk associated with chemical mixtures is set forth in section 3 of this preamble discussion.

EPA also requests comments on whether the additivity concept should be applied only to a limited (i.e., finite) number of the carcinogens in ambient waters that individually pose the greatest cancer risk to exposed populations rather than to all detected carcinogens. For example, the narrative criteria could be interpreted such that the cumulative cancer risk posed by the presence of five (or some other number of) carcinogens in any given waterbody or segment would not exceed 10^{-5}. Such a modification would reflect the fact, recognized in EPA's 1986 Guidelines for the Health Risk Assessment of Chemical Mixtures, that as the number of pollutants covered by the additivity assumption increases, the uncertainty associated with the resulting risk assessment is also likely to increase. This approach could also greatly ease the administrative burden of preparing total maximum daily loads (TMDLs) and water quality-based effluent limits (WQBELs) based on the additivity assumption, since it would provide a cut-off to what otherwise might be an extended inquiry and would relieve regulatory authorities of the burden of identifying risks and sources associated with carcinogens that pose a relatively insignificant risk to human health. Finally, EPA requests comments on whether a separate water quality criterion (WQC) should be established for carcinogenicity (e.g., total cancer risk for ambient waters not to exceed 10^{-4}, 10^{-5}, or some other cancer risk level) rather than the approach discussed above for implementing narrative criteria.

These alternatives differ considerably from the proposal of the Committees of the Initiative with respect to considering additivity for carcinogens. The Committees proposed that the additivity assumption be applied only with respect to facilities otherwise requiring WQBELs for individual carcinogens, and only as to those carcinogens requiring WQBELs. Thus, the Committees did not propose application of the additivity assumption in setting or interpreting ambient water quality criteria. Rather, their proposed approach would have resulted in further limitations beyond WQBEL levels so that the carcinogens covered by WQBELs from a given facility would not, after mixing with receiving waters, represent a total cancer risk greater than 10^{-5}. Thus, the Committees' approach did not address carcinogens for which WQBELs were not needed. In addition, because not all sources discharging a pollutant for which WQBELs are needed necessarily need WQBELs in order to provide for attainment of water quality standards, not all sources discharging a given carcinogen would have the additivity assumption applied to their discharges.

Although EPA agrees that the approach proposed by the Committees of the Initiative offers certain administrative advantages as compared with other alternatives, EPA is concerned that the Committees' approach could be inequitable in its application. The full text of the proposal of the Committees is reproduced below under section 4 of this preamble. EPA invites comment on the possible use of that approach in the final rule to account for the additive effects of carcinogens in the Great Lakes.

c. *Human Health—Non-carcinogens.* The 1986 EPA guidelines on chemical mixtures acknowledge that additivity of effects for non-carcinogens is most appropriate when pollutants in a mixture elicit the same type of effect by the same mechanism of action. However, because information on the mechanism of action is rather limited for many pollutants, the 1986 EPA guidelines on chemical mixtures recommend that when two or more compounds produce adverse effects on the same organ system (i.e., target organ) the effects should be considered additive. The 1986 guidelines additionally state that additivity for dissimilar effects does not have strong scientific support. Thus, the underlying assumption in the 1986 guidelines is that the components of a mixture which produces adverse effects on the same target organ are additive. This approach could overestimate or underestimate the actual risks due to possible antagonistic or synergistic interactions among components in a mixture.

The 1986 guidelines recommend the use of a hazard index (HI) approach for non-carcinogenic toxic agents. The hazard index indicates if there is a concern with a mixture by providing a rough measure of likely toxicity. However, it does not define dose-response relationships (i.e., its numerical value is not a direct estimate of risk).

EPA solicits comment on the HI approach for applying additivity to non-carcinogenic effects, as described in the 1986 guidelines. This approach assumes that multiple, simultaneous exposures to a chemical could result in an adverse health effect and that the magnitude of the effect is proportional to the sum of

the ratios of the actual exposures to "acceptable" exposures. When the HI exceeds unity (i.e., 1) a potential for adverse health effects exists. While any single chemical with an exposure level greater than the toxicity value (i.e., threshold or Reference dose (RfD)) will cause the HI to exceed unity, for mixtures, the HI can also exceed unity even if no single chemical exceeds its RfD.

The hazard index approach assumes dose addition for those compounds that induce the same target organ response and, therefore, a separate hazard index should be developed for each end point. Dose addition (additivity) for dissimilar effects does not have strong scientific support. For estimating the "HI" of a mixture of non-carcinogens based on additivity, the following equation may be applied:

$$HI = \frac{E_1}{RfD_1} + \frac{E_2}{RfD_2} + \cdots + \frac{E_n}{RfD_n}$$

Where, for i = 1 through n:

E_i = exposure level of the chemical in the mixture.

RfD_i = The Reference dose for that chemical.

Since publication of the 1986 guidelines, EPA has published a "Technical Support Document on Risk Assessment of Chemical Mixtures (November 1988)", which discusses the hazard index approach as well as an alternative "toxicity equivalency factor" (TEF) approach. This document is available in the administrative record for this rulemaking. The "toxicity equivalency factor" approach was not discussed in the 1986 guidelines but has since been recommended by EPA for risk assessment of certain chemical classes. One advantage of the TEF approach is that it allows the use of data to assess and quantify the toxicity of mixtures that are not used to quantify the risk from exposure to single chemicals (i.e., acute data, data from atypical routes of environmental exposure and *in vitro* data). The 1988 Technical Support Document states that the TEF approach should be applied only to compounds that have the same mode of action or act independently. The approach described in the 1988 Technical Support Document is more restrictive than the 1986 guidelines in the use of the additivity assumption for non-carcinogens but it is consistent with the proposal for the use of TEFs made by the Committees of the Initiative. EPA also believes that the approach in the 1988 Technical Support Document is not inconsistent with the original 1986 guidelines which state: "No single approach can be recommended to risk assessments for multiple chemical exposures."

The preferred approach presented in the 1986 guidelines for conducting risk assessment of mixtures is to use *in vivo* toxicity data on the mixture itself based on the route of exposure and duration period of concern. However, this approach is not practical in most cases because adequate toxicity data are available on very few complex mixtures. The "toxicity equivalency factor" approach involves estimating the potency of less well-studied components in a mixture relative to the potency of better studied components, using data from comparable types of *in vitro* and short-term *in vivo* assays. So far, this approach has been used only to estimate the toxicity of mixtures of chlorinated dioxins and dibenzofurans by using extensive data on the *in vitro* activity of these compounds. Today's proposal requests comments on whether EPA should consider the "toxicity equivalency factor" approach for these chemical classes and for any other mixtures for which TEFs may reasonably be calculated in the future as this area of research progresses and EPA is able to develop additional TEFs.

EPA specifically solicits comment on two possible approaches to addressing additivity for non-carcinogens, set forth in sections 3 and 4 of this preamble. Both would require that mixture of CDDs and CDFs be considered additive, in accordance with specific TEFs described in more detail in section 2.d. of the preamble. In addition, the option described in section 3 would require use of bioaccumulation equivalency factors (BEFs) (discussed in detail below) to account for differences in bioaccumulation potential of different CDDs and CDFs. The alternative set forth in section 3 would require generally that noncancer effects be considered additive for those pollutants for which available scientific information supports a reasonable assumption that the pollutants produce the same adverse effects through the same mode of action, and for which TEFs and BEFs may reasonably be calculated. Thus, this option would establish a general requirement for States and Tribes to develop specific additivity protocols for classes of pollutants when sufficiently supported by scientific information.

The second option which EPA specifically solicits comment on is set forth in section 4. It would require application of additivity assumptions only for those pollutants for which TEFs are set forth as part of the Great Lakes Guidance. Pollutants covered initially would include CDDs and CDFs, but more pollutants could be addressed through future revisions to the rule. This option would best promote consistency among the Great Lakes States and Tribes, but may involve more lag time between availability of scientific support for application of additivity and use in water quality management than would the option set forth in section 3.

d. *TEFs and BEFs for Chlorinated Dibenzo-p-dioxins (CDDs) and Chlorinated Dibenzofurans (CDFs).* Chlorinated dibenzo-p-dioxins and dibenzofurans (CDDs/CDFs) constitute a family of 210 structurally related chemical compounds. During the late 1970s and early 1980s, EPA encountered a number of incidents of environmental pollution in which the toxic potential of CDDs and CDFs figured prominently. Initially, concern was focused solely on 2,3,7,8-TCDD, which was produced as a low level by-product during the manufacture of certain herbicides.

During the past 20 years, many studies have been conducted to elucidate the toxic effects of 2,3,7,8-TCDD. The data obtained from these studies are summarized in a number of reviews (U.S. EPA, 1984; U.S. EPA, 1985; U.S. EPA, 1988; WHO, 1977; NRCC, 1981), which are available in the administrative record for this rulemaking. EPA is currently engaged in a major effort to generate more data on dioxin toxicity, and to update its analysis of existing data. While research efforts to date have not answered all of the questions, the data do show that 2,3,7,8-TCDD can produce a variety of toxic effects, including cancer and reproductive effects in laboratory animals at very low doses.

Data on the toxicity of other CDDs and for CDFs is considerably more limited. These data are summarized in two EPA documents entitled "Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans (CDDs and CDFs)", (October 1986), and "1989 Update to the Interim Procedures for Estimating Risks Associated with Exposures to Mixtures of Chlorinated Dibenzo-p-Dioxins and -Dibenzofurans (CDDs and CDFs)", (March 1989) (the "1989 TEF Update"), which are available in the administrative record for this rulemaking. While data available from long-term *in vivo* studies are limited for the majority of CDDs and CDFs, a much larger body of data is available on short-term *in vivo* studies and a variety of *in vitro* studies. These experiments cover a wide variety of end points; e.g., developmental toxicity, cell

transformation, and enzyme induction (aryl hydrocarbon hydroxylase [AHH]). While the doses necessary to elicit the toxic response differ in each case, the relative potency of the different compounds compared to 2,3,7,8-TCDD is generally consistent from one end point to another.

This information, developed by researchers in several laboratories around the world, reveals a strong structure-activity relationship between the chemical structure of a particular CDD or CDF congener and its ability to elicit a biological or toxic response in various *in vivo* and *in vitro* test systems. (Bandiera et al., 1984; Olson et al., 1989; U.S. EPA 1989; NATO/CCMS 1988a,b). Research has also revealed a mechanistic basis for these observations. That is, a necessary (but not sufficient) condition for expression of much of the toxicity of a given CDD or CDF congener is its ability to bind with a particular protein receptor located in the cytoplasm of the cell. This congener receptor complex then migrates to the nucleus of the cell, where it initiates reaction leading to expression of toxicity (Poland and Knutson, 1982).

Based on this type of information, scientists suggested the development of numerical factors ("toxic equivalency factors" or "TEFs") that could be used to equate the toxicity posed by various CDDs and CDFs to 2,3,7,8-TCDD for purposes of conducting risk assessments including mixtures of the chemicals. EPA developed an interim procedure that was reviewed and approved by EPA's Science Advisory Board, and published as a monograph of EPA's Risk Assessment Forum in 1987. The procedure was modified in certain respects in the 1989 TEF Update, and has been adopted for international use by the North Atlantic Treaty Organization.

EPA solicits comment on whether EPA should require use of the specified TEF-based approach to equate mixtures of CDDs and CDFs to a concentration of 2,3,7,8-TCDD for purposes of implementing the human health and wildlife criteria for 2,3,7,8-TCDD. Specific options are set forth in sections 3 and 4 of this preamble. The TEFs are the same as those set forth in EPA's 1989 TEF Update, and that Update provides the technical basis for the proposal. EPA also invites comment on whether other TEFs should be used rather than those listed in the 1989 TEF Update.

The CDD/CDF TEFs address the toxicity of various chemicals as compared to 2,3,7,8-TCDD, but do not address differences in bioaccumulation potential between the chemicals. Because the criteria for 2,3,7,8-TCDD are largely driven by the relatively large bioaccumulation factor for the chemical, and because available information suggests that other CDDs and CDFs have different bioaccumulation factors, EPA believes that it may be appropriate to use factors accounting for the different BAFs in converting concentrations of CDDs and CDFs to equivalent concentrations of 2,3,7,8-TCDD. The option set forth in section 3 incorporates this approach. The technical rationale for the particular "bioaccumulation equivalency factors" (BEFs) selected is provided in a "Draft Technical Support Document for Bioaccumulation Equivalency Factors," which is available in the administrative record for this rulemaking.

The Committees of the Initiative did not propose use of bioaccumulation equivalency factors; their proposal would have assumed that BAFs for all CDDs and CDFs are identical to that calculated for 2,3,7,8-TCDD. Because available information on BAFs for other CDDs and CDFs suggests that BAFs for those chemicals are generally smaller than for 2,3,7,8-TCDD, the Committee's proposal would be a conservative, as well as a simplifying, approach. EPA solicits comment on this option, set forth in section 4 of this preamble.

e. *Wildlife.* As stated earlier, EPA has no present policy on the use of additivity for wildlife effects. EPA solicits comment, however, on whether additivity with respect to wildlife effects should be treated in a manner consistent with the options described above for noncancer human health effects and for mixtures of CDDs and CDFs. EPA believes that an argument can be made that the TEFs for CDDs and CDFs developed for use in human health risk assessments should generally be applicable to wildlife, since the TEFs are based largely on animal studies. Using the TEF approach, the total allowed exposure level for mixtures of these congeners would not exceed the level established by the wildlife criteria for 2,3,7,8-TCDD, based on 2,3,7,8-TCDD equivalents. Two specific alternatives regarding application of additivity principles to wildlife effects are set forth in sections 3 and 4 of this preamble. EPA requests comment on these options, and on possible alternatives to them.

In developing this proposed Guidance, the use of TEFs for polychlorinated biphenyls (PCB) congeners for wildlife was considered. In December 1990, EPA's Risk Assessment Forum held a workshop to specifically address the use of TEFs for PCBs (Risk Assessment Forum, Workshop Report on Toxicity Equivalency Factors for Polychlorinated Biphenyl Congeners, June 1991, EPA/625/3–91–020). This workshop concluded that the application of TEFs to PCBs is not as straightforward as it is in the case of CDDs and CDFs, but that TEFs for dioxin-like PCB congeners are feasible and may be considered additive with those for CDDs and CDFs. Further, the workshop concluded that current dioxin-like TEFs appear to be useful in assessing traditional measures of wildlife toxicity. The workshop, however, recommended that a TEF scheme for PCBs should be seen as an interim procedure and promising bioassay approaches should also be vigorously pursued.

On March 19–20, 1992, a Dioxin Ecotox Subcommittee of the Ecological Processes and Effects Committee of the Science Advisory Board met to review EPA's research proposals to support the development of an ambient aquatic life water quality criterion for 2,3,7,8–TCDD. At that meeting, the Subcommittee addressed the general issue of research needed to support the use of TEFs for aquatic life and wildlife. In their final report dated August 1992, the Committee stated that the TEF approach appears promising for aquatic life and wildlife but more studies are needed to show phylogenetic variability. The Committee concluded that at the present time there are insufficient data available to judge the reliability and the accuracy of the TEF approach.

A recent study of the potencies of CDDs, CDFs and PCBs relative to 2,3,7,8–TCDD for producing early life stage mortality in rainbow trout calculated TEFs for each of these classes of chemicals (Walker and Peterson, 1991). The TEFs calculated in this study for CDDs and CDFs were similar to those proposed by Safe (1990). However, the TEFs for the PCB congeners were 14 to 80 times less than those proposed in Safe (1990). The results of the Walker and Peterson study illustrate the significant uncertainties in applying TEFs across species and endpoints for PCB congeners. Further, another recent study concluded that the TEFs proposed in Safe (1990) for the "dioxin-like" PCBs overestimate the potency of these compounds by a factor of 10–1,000 (DeVito et al., 1992).

EPA solicits comments on whether TEFs for PCBs should be included together with those for CDDs and CDFs in the use of the additivity concept for wildlife effects. Table VIII.D–1 presents TEFs for PCB congeners from Safe, 1990. EPA specifically requests

comment on the inclusion of these TEFs for wildlife in the Great Lakes Guidance.

TABLE VIII.D–1.—TOXIC EQUIVALENCY FACTOR VALUES FOR PCBs

	IUPAC #	TEF Value
(a) Coplanar PCBs:		
3,3',4,4',5–PeCB	126	0.1
3,3',4,4',5,5'-HxCB	169	.05
3,3',4,4'-TCB	77	.01
(b) Monoortho Coplanar PCBs:		
2,3,3',4,4'-PeCB	105	.001
2,3,4,4'-PeCB	114	.001
2',3,4,4',5–PeCB	123	.001
2,3',4,4',5–PeCB	118	.001
2,3,3',4,4',5–HxCB	156	.001
2,3,3',4,4',5–HxCB	157	.001
2,3',4,4',5,5'-HxCB	167	.001
2,3,3',4,4',5,5'-HpCB	189	.001

3. Request for Comment on Approach Considered for Implementing the States' Narrative Criteria

The text presented below represents one approach that would specify that the narrative criteria be interpreted to account for the additive effects of chemicals. EPA requests comments on whether the language below should be added to the Implementation Procedures of the final Guidance.

The following procedures establish the manner in which the additive effects of chemical mixtures shall be treated when interpreting the narrative criteria of the States and Tribes requiring that all waters be free from substances that injure or are toxic or produce adverse physiological responses in humans, animals or plants.

A. *Aquatic Life Effects.* Whole-effluent toxicity requirements established under procedure 6 of appendix F of part 132 shall be used to account for additive effects to aquatic organisms.

B. *Wildlife Effects.* The effects of individual pollutants shall be considered additive for chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans, and for other pollutants for which available scientific information supports a reasonable assumption that the pollutants produce the same adverse effects through the same mechanism of action, and for which toxic equivalency factors and bioaccumulation equivalency factors may reasonably be calculated. For chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans, additivity shall be accounted for in accordance with section E. For other pollutants, toxic equivalency factors and bioaccumulation equivalency factors shall be developed and thereafter applied in a manner similar to that described in section E based either on a relationship to 2,3,7,8-TCDD or to some other chemical, as appropriate.

C. *Human Health—Non-cancer Effects.* The effects of individual pollutants shall be considered additive for chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans, and for other pollutants for which available scientific information supports a reasonable assumption that the pollutants produce the same adverse effects through the same mechanism of action, and for which toxic equivalency factors and bioaccumulation equivalency factors may reasonably be calculated. For chlorinated dibenzo-p-dioxins and chlorinated dibenzofurans, additivity shall be accounted for in accordance with section E. For other pollutants, toxic equivalency factors and bioaccumulation equivalency factors shall be developed and thereafter applied in a manner similar to that described in section E based either on a relationship to 2,3,7,8-TCDD or to some other chemical, as appropriate.

D. *Human Health—Cancer Effects.* The incremental cancer risk of each carcinogen shall be considered to be additive and the total cancer risk shall not exceed 10^{-5}. However, the State or Tribe may determine, based on information submitted by a permittee or otherwise available to the State or Tribe, that the carcinogenic risk for a given mixture is not additive.

E. *Toxicity Equivalency Factors.* The following TEFs shall be used when implementing human health or wildlife criteria for 2,3,7,8-TCDD. The concentration of each CDD and CDF in an effluent shall be converted to a 2,3,7,8-TCDD equivalent concentration by multiplying the concentration of the CDD or CDF by the TEF shown in Table VIII.D.2 below, and multiplying that product by the bioaccumulation equivalency factor in Table VIII.D.3 below. All resultant concentrations shall be added to produce an equivalent 2,3,7,8-TCDD concentration. The equivalent 2,3,7,8-TCDD concentration shall be used to establish TMDLs (including wasteload and load allocations) pursuant to procedure 3. This equivalent 2,3,7,8-TCDD concentration shall also be used as the concentration of 2,3,7,8-TCDD for purposes of assessing the total cancer risk of carcinogens pursuant to section 4.D.

TABLE VIII.D–2.—TOXIC EQUIVALENCY FACTOR VALUES FOR CDDs AND CDFs

Congener	TEF
2,3,7,8–TCDD	1.0
1,2,3,7,8–PeCDD	.5
1,2,3,4,7,8–HxCDD	.1
1,2,3,6,7,8–HxCDD	.1
1,2,3,7,8,9–HxCDD	.1
1,2,3,4,6,7,8–HpCDD	.01
OCDD	.001
2,3,7,8–TCDF	.1
1,2,3,7,8–PeCDF	.05
2,3,4,7,8–PeCDF	.5
1,2,3,4,7,8–HxCDF	.1
1,2,3,6,7,8–HxCDF	.1
2,3,4,6,7,8–HxCDF	.1
1,2,3,7,8,9–HxCDF	.1
1,2,3,4,6,7,8–HpCDF	.01
1,2,3,4,7,8,9–HpCDF	.01
OCDF	.001

TABLE VIII.D–3.—BIOACCUMULATION EQUIVALENCY FACTORS (BEFs)

Congener	TCDD BEF
2,3,7,8–TCDD	1.0
1,2,3,7,8–PeCDD	≤0.8
1,2,3,4,7,8–HxCDD	≤0.3
1,2,3,6,7,8–HxCDD	≤0.2
1,2,3,7,8,9–HxCDD	≤0.2
1,2,3,4,6,7,8–HpCDD	≤0.03
OCDD	≤0.02
2,3,7,8–TCDF	1.2
1,2,3,7,8–PeCDF	0.3
2,3,4,7,8–PeCDF	1.8
1,2,3,4,7,8–HxCDF	≤0.3
1,2,3,6,7,8–HxCDF	≤0.3
2,3,4,6,7,8–HxCDF	≤0.5
1,2,3,7,8,9–HxCDF	≤0.5
1,2,3,4,6,7,8–HpCDF	≤0.003
1,2,3,4,7,8,9–HpCDF	≤0.1
OCDF	≤0.005

Notes:
1. $^{X}BEF \times {}^{TCDD}BAF = {}^{X}BAF$
2. ^{X}BAF = lipid-based bioaccumulation factor for total congener concentration in water.

The TEFs provided in Table VIII.D–2 are the same as those set forth in EPA's 1989 TEF Update. However, this Table has been reorganized to make it consistent with Table VIII.D–3 above (which lists the BEFs for specific congeners and does not include CDDs and CDFs with TEF values of zero).

4. Request for Comment on Alternative Approach

The text presented below represents the proposal for additivity of the Committees of the Initiative, modified by EPA to delete the application of TEFs for PCBs to wildlife. EPA requests comments on whether the language below should be added to the implementation procedures of the final Guidance.

The toxic action of some pollutants in mixtures is additive in their effects on organisms. The following procedure establishes the manner in which the additive effects of chemical mixtures shall be treated. This provision shall be applied to point source discharges.

A. *Aquatic Life Effects.* Whole-effluent toxicity requirements established under procedure 6 of appendix F of part 132 shall be used to account for additive effects to aquatic organisms.

B. *Wildlife Effects.* When establishing wasteload allocations (WLAs) for the protection of wildlife, the effects of individual pollutants shall be considered additive for the pollutants for which toxicity equivalency factors (TEFs), as provided in section E of this procedure, are available.

C. *Human Health—Non-cancer Effects.* When establishing wasteload allocations (WLAs) for the protection of human health for non-carcinogens, the effects of individual pollutants shall be considered additive for the pollutants for which toxicity equivalency

factors, as provided in part F of this procedure, are available.

D. *Human Health—Cancer Effects.* When establishing wasteload allocations (WLAs) for the protection of human health for carcinogens, the following shall apply:

(1) Except as noted in (2) below, in cases where an effluent contains detected levels of more than one pollutant for which a Tier I criterion or Tier II value exists and for which a water quality-based limitation is required under Procedure 5, the incremental risk of each carcinogen shall be considered to be additive and the total cancer risk shall not exceed 10^{-5}. The wasteload allocation (WLA) for each carcinogen shall be established in a permit to protect against potential additive effects associated with simultaneous, multiple-chemical human exposure such that the following condition is met:

$$\frac{C_1}{WLA_1}+\frac{C_2}{WLA_2}+\cdots+\frac{C_n}{WLA_n}\leq 1$$

Where:

$C_1 \ldots n$ = the monthly average effluent limitation expressed as concentration of each separate carcinogen in the effluent.

$WLA_1 \ldots n$ = the wasteload allocation concentration calculated for each substance at each permitted facility independent of other carcinogens that may be present in the receiving waters based on the human cancer criterion for each respective carcinogen.

(2) If the permitting authority determines, based on information submitted by the permittee, that the carcinogenic risk for a mixture is not additive, the permitting authority may establish wasteload based on that information.

E. *TEFs applied to Wildlife Effects.* The permitting authority shall use toxicity equivalency factors when establishing wasteload allocations for the protection of wildlife for chlorinated dibenzodioxins (CDDs) and chlorinated dibenzofurans (CDFs). The concentration of each CDD and CDF in an effluent shall be converted to a 2,3,7,8-TCDD equivalent concentration by multiplying the concentration of the CDD or CDF by the TEF shown in Table VIII.D.4. All resultant concentrations shall be added to produce an equivalent 2,3,7,8-TCDD concentration. The equivalent 2,3,7,8-TCDD concentration shall be used to establish a wasteload allocation consistent with procedure 3. Whenever one or more CDDs and/or CDFs are present in an effluent, the permitting authority shall establish a wasteload allocation for 2,3,7,8-TCDD. The permittee shall be considered in compliance only if the sum of the effluent concentration times the TEF for all the CDDs and CDFs are less or equal to the wasteload allocation for 2,3,7,8-TCDD. If there are carcinogens other than CDDs and CDFs in the effluent, the sum calculated for the equivalent 2,3,7,8-TCDD concentration must be used in the formula in D(1) above for C_k, where k represents 2,3,7,8-TCDD.

F. *TEFs applied to Human Health—Cancer Effects.* The permitting authority shall use toxicity equivalency factors when establishing wasteload allocations for human health-based criteria for CDDs and CDFs. The concentration of each CDD and CDF in an effluent shall be converted to a 2,3,7,8-TCDD equivalent concentration by multiplying the concentration of the CDD or CDF by the TEF shown in Table VIII.D.4. All resultant concentrations shall be added to produce an equivalent 2,3,7,8-TCDD concentration. The equivalent 2,3,7,8-TCDD concentration shall be used to establish a wasteload allocation consistent with procedure 3. Whenever one or more CDDs and/or CDFs are present in an effluent, the permitting authority shall establish a wasteload allocation for 2,3,7,8-TCDD. The permittee shall be considered in compliance only if the sum of the effluent concentration times the TEF for all the CDDs and CDFs are less or equal to the wasteload allocation for 2,3,7,8-TCDD. If there are carcinogens other than CDDs and CDFs in the effluent, the sum calculated for the equivalent 2,3,7,8-TCDD concentration must be used in the formula in D(1) above for C_k, where k represents 2,3,7,8-TCDD.

TABLE VIII.D–4.—TOXIC EQUIVALENCY FACTOR VALUES FOR CDDS AND CDFS

Compound	TEF value
1. Dioxins:	
Mono-, Di-, and TriCDDs	0
2,3,7,8–TCDD	1
Other TCDDs	0
2,3,7,8,-PeCDD	0.5
Other PeCDDs	.0
2,3,7,8–HxCDDs	.1
Other HxCDDs	.0
2,3,7,8–HpCDD	.01
Other HpCDDs	.0
OCDD	.001
2. Furans:	
Mono-, Di-, and TriCFDs	0
2,3,7,8–TCDF	0.1
Other TCDFs	.0
2,3,4,7,8–PeCDF	.5
1,2,3,7,8–PeCDF	.05
Other PeCDFs	.0
2,3,7,8–HxCDFs	.1
Other HxCDFs	.0
2,3,7,8–HpCDFs	.01
Other HpCDFs	.0
OCDF	.001"

5. Request for Comments

EPA requests comment on each element of the text for the two approaches to additivity presented in sections 3 and 4 above, including all subjects and issues raised in the preamble discussion whether or not specific regulatory text has been provided in the proposed Guidance, and any suggested alternative requirements or combinations of requirements to address these elements and issues in the final rule. EPA may promulgate final rules based on any of the issues or subjects discussed in this preamble or based on a combination of possible requirements to address these subjects and issues.

E. Reasonable Potential for Exceeding Numeric Water Quality Standards

The purpose of this section is to define the proposed procedures for determining whether an NPDES permit for discharges to the Great Lakes System must include a water quality-based effluent limitation for a parameter or pollutant parameter (not including whole effluent toxicity). Considerations related to whole effluent toxicity and the basis for such considerations are addressed separately in section G of this preamble. The proposed Guidance would require permitting authorities to follow specific procedures where facility-specific effluent monitoring data is available. Where this data is not available, including when all available effluent data for a pollutant or pollutant parameter is below the applicable analytical detection level, this Guidance does not establish any new or specific requirements, and permitting authorities will continue to follow existing Federal, State or Tribal regulations and guidance. Existing guidance for determination of reasonable potential in the absence of facility-specific effluent monitoring data are discussed in section 5.E.1 of the preamble, below.

1. Existing National Rules and Guidance

EPA's existing regulations require NPDES permits to contain effluent limitations necessary to meet applicable technology-based requirements of Federal and State law. These technology-based limitations are derived directly from application of National effluent limitation guidelines or on the basis of the permitting authority's best professional judgment (40 CFR 125.3). States are currently required to adopt regulations consistent with these provisions as part of their approved NPDES State permitting program (40 CFR 123.25(a)(36)). EPA is not proposing to amend the requirements governing the establishment of technology-based limitations in to the proposed Guidance.

In addition to these technology-based requirements, EPA's existing regulations require NPDES permits to include water quality-based effluent limitations (WQBELs) to control all pollutants or pollutant parameters which the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any water quality standard, including numeric and narrative criteria for water quality (40 CFR 122.44(d)(1)).

When determining whether a discharge will cause, has the reasonable potential to cause, or contributes to an excursion above any State or Tribal water quality standard, the permitting authority must use all relevant available data, including facility-specific effluent monitoring data where available. Additionally, the permitting authority must use procedures which account for existing controls on point and nonpoint sources of pollution; variability of the pollutant or pollutant parameter in the effluent; and, where appropriate, the dilution of the effluent in the receiving water (40 CFR 122 44(d)(1)(ii)). If the permitting authority determines that a discharge has the reasonable potential to cause or contribute to an excursion of an applicable numeric or narrative water quality criterion, it must include a WQBEL for the individual pollutant in the permit (40 CFR 122.44(d)(1)(iii)). In the absence of a numeric water quality criterion for an individual pollutant under these circumstances, the permitting authority must derive appropriate WQBELs from the State or Tribal narrative water quality criterion by: using a calculated numeric criterion for the pollutant that attains the applicable narrative criterion and protects designated uses; establishing effluent limitations on a case-by-case basis using EPA's water quality criteria developed under section 304(a) of the Clean Water Act, supplemented with other information where necessary; or establishing effluent limitations on an indicator pollutant (40 CFR 122.44(d)(1)(vi)).

EPA has provided guidance on how to apply these requirements in the "Technical Support Document for Water Quality-based Toxics Control (TSD)" (EPA/505/2–90–001, March 1991), which is available in the administrative record for this rulemaking. Copies are also available upon written request from the person listed in section XIII of this preamble. In the TSD, EPA recommends that facility-specific effluent monitoring data be used, where available, to project receiving water concentrations, which are then compared to water quality criteria. This comparison in the TSD guidance is comprised first of calculating the pollutant concentration in the receiving water after considering dilution (if allowed by the water quality standards regulation), the contributions of other point and nonpoint sources, and the potential for effluent variability to justify higher effluent concentrations than have actually been measured; and second, comparing this calculation to the applicable water quality criterion. The TSD guidance allows the permitting authority the flexibility to determine the appropriate approach for assessing reasonable potential. For example, an authority may opt to use a stochastic dilution model that incorporates both ambient dilution and effluent variability rather than use a steady state dilution model with a statistically defined maximum effluent concentration. Also, a permitting authority may develop a WQBEL in the absence of facility-specific effluent monitoring data. Whatever approach is selected by the authority, it must satisfy all requirements of 40 CFR 122.44(d)(1)(ii) summarized above.

One of four outcomes will be reached when using the TSD protocol:

a. *Excursion Above the Water Quality Standard.* If the permitting authority determines that pollutants or pollutant parameters in a facility's discharge are or may be discharged at a level which causes or contributes to an excursion above a narrative or numeric water quality criterion, it must establish a WQBEL in the permit for those pollutants (40 CFR 122.44(d)(1)(i).

b. *Reasonable Potential for Excursion Above the Water Quality Standard.* If the permitting authority determines that pollutants or pollutant parameters in a facility's discharge are or may be discharged at a level which has the reasonable potential to cause or contribute to an excursion above a narrative or numeric water quality criterion, it must establish a WQBEL in the permit for that pollutant (40 CFR 122.44(d)(1)(i)). EPA believes that reasonable potential is shown where an effluent in conjunction with other sources of a pollutant is projected to cause an excursion above the water quality criterion. This projection is based upon an analysis of available data that accounts for limited sample size and effluent variability. EPA's guidance in the TSD does not, however, constrain the determination of reasonable potential to a projection of an excursion above a water quality criterion based solely on effluent variability. The guidance recognizes that reasonable potential determinations include consideration of the factors in 40 CFR 122.44(d)(1)(ii) and any other appropriate factors based on the professional judgement of the permitting authority. These other factors may include the existing data on toxic pollutants; type of receiving water and designated uses (e.g., high-use fishery); relative proximity to the water quality standard; existing controls on point and nonpoint sources; compliance history of the facility; and type of treatment facility.

c. *No Reasonable Potential for Excursions Above the Water Quality Standards.* If the permitting authority determines that the pollutants or pollutant parameters in a facility's discharge are not discharged at a level that have the reasonable potential to cause or contribute to an excursion above a narrative or numeric water quality criterion, then a WQBEL for those pollutants is not necessary. In these situations, EPA's guidance recommends that the effluent monitoring be repeated at a frequency of at least once every five years (see TSD at p. 64).

d. *Inadequate Information.* If a permitting authority has inadequate information to determine whether a discharge contains pollutants or pollutant parameters which are or may be discharged at a level which has the reasonable potential to cause or contribute to an excursion of a narrative or numeric water quality criterion, EPA's existing guidance recommends that the permit contain appropriate monitoring requirements and a reopener clause (see TSD at p. 64). This clause would require reopening of the permit and establishment of a WQBEL based upon any monitoring results or other new factors which substantiate that the effluent causes, has the reasonable potential to cause, or contributes to an excursion above water quality standards.

2. Proposed Procedure 5

Procedure 5 of the proposed Guidance requires the permitting authority to include a WQBEL in an NPDES permit whenever a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value. Procedure 5 of appendix F to part 132 sets forth a two-step process for determining whether the discharge of a pollutant will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value.

First, under procedure 5.A of appendix F, permitting authorities must develop preliminary effluent limitations that will ensure that all Tier I criteria and Tier II values will be met in-stream after discharge where there is sufficient data to develop such criteria or values. If such data do not exist, permitting authorities must apply the provisions in procedure 5.D of appendix F to determine whether such data must be generated. Second, procedure 5.B and 5.C of appendix F set forth procedures to be followed to determine: the

projected effluent quality (PEQ) of the effluent that will be discharged; and whether a WQBEL must be established based on specified ratios between the PEQ and the preliminary effluent limitation. If such effluent data do not exist or if all such effluent data for a pollutant or pollutant parameter are below the analytical detection level for that pollutant or pollutant parameter, permitting authorities will continue to apply existing Federal, State or Tribal regulations and guidance for making reasonable potential determinations. Finally, procedure 5.E of appendix F provides that, regardless of the manner in which the reasonable potential determination is made, all effluent limitations must also comply with all other applicable State, Tribal and Federal requirements.

The proposed Guidance provides permitting authorities with specific requirements for making reasonable potential determinations based on facility-specific effluent monitoring data consistent with the provisions of 40 CFR 122.44(d)(1)(i), (ii), (iii), and (vi). As discussed in section II.D of the preamble, the proposed Guidance requires the States and Tribes to adopt the Tier I criteria in Tables 1 through 4 of 40 CFR part 132 and the methodologies for deriving Tier I criteria and Tier II values in appendixes A, C, and D of 40 CFR part 132 into their water quality standards for the Great Lakes System. Part 132.3 of the proposed Guidance defines Tier I criteria as:

> * * * numeric values derived by use of the Tier I methodologies in appendixes A, C and D, the methodology in appendix B, and the procedures in appendix F, that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

Tier II values are defined as:

> * * * numeric values derived by use of the Tier II methodologies in appendixes A, C and D, the methodology in appendix B, and the procedures in appendix F, that are used to implement narrative water quality criteria.

Procedure 5 implements the provisions of 40 CFR 122.44(d)(1)(i) for discharges within the Great Lakes System by requiring that WQBELs be established whenever pollutants or pollutant parameters "are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any State water quality standard, including State narrative criteria for water quality." Procedure 5 of appendix F is also consistent with the provisions of 40 CFR 122.44(d)(1)(iii) requiring WQBELS be established whenever a discharge "causes, has the reasonable potential to cause, or contributes to an in-stream excursion above the allowable ambient concentration of a State numeric criterion" because the Tier I criteria will serve as minimum numeric water quality criteria for the Great Lakes System.

Procedure 5 of appendix F to part 132 is also consistent with the provisions of 40 CFR 122.44(d)(1)(vi)(A). This section requires authorities to establish WQBELS to implement narrative water quality criteria using one or more of the specified options. Option 122.44(d)(1)(A) allows the permitting authority to establish WQBELs using a calculated numeric water quality criterion for the pollutant that will attain and maintain applicable narrative criteria and fully protect the designated uses. The Guidance implements this option by providing Tier I and Tier II methodologies to translate narrative water quality criteria into numerical criteria or effluent limitations.

Finally, procedure 5 of appendix F to part 132 also includes consideration of controls on point and nonpoint sources and dilution (see procedure 5.A of appendix F) and effluent variability through statistical characterizations (see procedures 5.B and 5.C of appendix F), and is, therefore, consistent with the requirements of 40 CFR 122.44(d)(1)(ii).

The procedures of this section are not intended to implement the regulations at 40 CFR 122.44(d)(1) (iv) and (v) which pertain to whole effluent toxicity. These provisions are implemented by procedure 6 of appendix F of the proposed Guidance. Furthermore, the procedures of this section do not affect the permitting authorities' existing obligation to implement the regulations at 40 CFR 122.44(d)(1)(vii) which pertain to expression of WQBELs.

a. *Developing Preliminary Effluent Limitations.* Procedure 5.A of the proposed Guidance describes how the permitting authority must establish preliminary effluent limitations. For a specific water body or stream segment, the allowable total maximum daily load (TMDL) for a pollutant is defined as the sum of the individual wasteload allocations (WLAs) and load allocations (LAs); a margin of safety is included to ensure that allocated loads, regardless of source, will not produce an excursion above water quality standards. The WLAs are those portions of the TMDL assigned to point sources; the LAs are those portions of the TMDL assigned to nonpoint sources and background sources. (40 CFR 130.2(f)). In procedure 5.A of appendix F of the proposed Guidance, the permitting authority is required to develop preliminary wasteload allocations based upon and consistent with the wasteload allocation procedures defined in procedure 3 of appendix F of the proposed Guidance, and then develop preliminary effluent limitations based on the preliminary wasteload allocations.

Procedure 5.A.2 of appendix F of the proposed Guidance specifies the procedure for developing preliminary effluent limitations based on the preliminary wasteload allocations. The preliminary effluent limitations are expressed as either a single day value, a weekly average, or a monthly average, and are used in determining if a facility causes, has the reasonable potential to cause or contribute to excursions above water quality criteria by being compared to actual effluent information in procedure 5.B of appendix F. Because the preliminary effluent limitations are for use to compare to actual effluent information, the Guidance expresses the preliminary effluent limitations in the same form that effluent data are typically available to permitting authorities. Effluent information is typically available to permitting authorities either in the permit application or in the Discharge Monitoring Records (DMR). Both the application forms and DMRs require effluent concentrations to be reported as weekly and monthly averages for publicly owned treatment works (POTWs) and as single day values and monthly averages for non-POTW. The use of these single day values, weekly averages, and monthly averages allows for direct comparison of preliminary effluent limitations to effluent data without requiring additional manipulations or conversion of the effluent data. EPA believes that this reduces the burden to the permitting authorities and facilities in reviewing and using effluent concentration data in determining if a WQBEL is necessary.

Each preliminary wasteload allocation has a corresponding preliminary effluent limitation which matches to the extent possible the criterion (or value) and dilution basis used to develop the wasteload allocation. The preliminary effluent limitation based on wildlife criteria is expressed in proposed section 5.A.2 as a monthly average because the wasteload allocation is calculated using a 30-day (monthly) average flow under proposed procedure 3 of appendix F. The preliminary effluent limitation based on human health criteria is expressed as a monthly average because, although the wasteload allocation is calculated using a harmonic mean (annual) river flow, the monthly averaging period is the closest expression of the preliminary effluent

limitations to an annual average. The preliminary effluent limitation based on acute aquatic life criteria is expressed as a daily value to reflect that the criteria themselves are expressed as one-hour averages and the wasteload allocation is calculated using a seven-day (weekly) average river flow. The preliminary effluent limitation based on chronic aquatic life criteria is expressed as a weekly average value to reflect that the criteria themselves are expressed as four-day averages and the wasteload allocation is calculated using a seven-day (weekly) average river flow. In addition, the preliminary effluent limitation based on chronic aquatic life criteria can as an option be expressed as a monthly average value to reflect that weekly average effluent data may not be available for non-POTW facilities.

Because the preliminary effluent limitations are based on the preliminary wasteload allocations, procedure 5.A.1 of appendix F accounts for dilution and existing controls on point and nonpoint sources of pollution, two of the required factors of federal NPDES regulations at 40 CFR 122.44(d)(1)(ii). The remaining factor of 40 CFR 122.44(d)(1)(ii), the potential for effluent variability, is accounted for in procedures 5.B and 5.C of appendix F of the proposed Guidance.

The proposed procedures in procedure 5.A of appendix F are limited to determination of the need for a WQBEL. Procedures for converting wasteload allocations into WQBELs and for expressing effluent limitations in NPDES permits shall continue to be governed by existing State, Tribal and Federal requirements or guidance (see 40 CFR 122.45(d) and (e)).

EPA invites comment on all aspects of the proposed methodology for calculating a preliminary effluent limitation, including the appropriateness of specifying a methodology and any suggested alternative methodologies. In particular, EPA invites comment on whether the preliminary effluent limitation needs to be expressed using exactly the same terms as the wasteload allocation (e.g., an annual average preliminary effluent limitation based on a wasteload allocation for human health protection). EPA also invites specific comment on the use of probabilistic or dynamic modeling procedures to calculate the preliminary wasteload allocations instead of the procedures proposed in procedure 3 of appendix F.

b. *Determining Whether There is Reasonable Potential to Exceed the Preliminary Effluent Limitations.* Procedures 5.B and 5.C of appendix F of the proposed Guidance specify procedures for determining the Projected Effluent Quality (PEQ) based on facility-specific effluent monitoring data. Available effluent monitoring data includes information from discharge monitoring reports (DMRs), data from NPDES permit application forms 2A and 2C, and other data requested of or submitted by the facility or available to the permitting authority. Procedures 5.B and 5.C of appendix F specify procedures for determining the PEQ in three different situations: procedure 5.B.1 of appendix F addresses situations where ten or more effluent data points are available and the effluent flow rate is less than the seven-day, 10-year low flow rate of the stream or the discharge is to the Open Waters of the Great Lakes; procedure 5.B.2 of appendix F addresses situations where ten or more effluent data points are available and the effluent flow rate is equal to or greater than the seven-day, 10-year low flow of the stream; and procedure 5 C of appendix F addresses situations where at least one but less than ten data points exist, regardless of the effluent flow rate.

i. *Determining Reasonable Potential Where Ten or More Effluent Data Points are Available and the Effluent Flow Rate is Less than the 7-day, 10-year Flow Rate or the Discharge is to Open Waters of the Great Lakes.* Procedure 5.B.1 of appendix F to part 132 provides two alternative methods of developing the PEQ for discharges to the open waters of the Great Lakes or to free flowing streams where the effluent flow rate is less than the stream seven-day, 10-year flow. The first method, which is set forth at procedures 5.B.1.a through c of appendix F, requires the PEQ to be specified as: The greater of the maximum daily effluent concentration or the 99th percentile of the distribution of the daily data; the 99th percentile of the distribution of monthly averages; and the 99th percentile of the distribution of weekly averages. Under this first method, a WQBEL must be established if the maximum effluent concentration or the 99th percentile of the available daily data exceeds the preliminary effluent limitation based on the criteria and values for the protection of aquatic life from acute effects; the 99th percentile of the distribution of monthly averages exceeds the preliminary effluent limitation based on criteria and values to protect aquatic life from chronic effects, human health or wildlife; or the 99th percentile of the distribution of weekly averages exceeds the preliminary effluent limitation based on the criteria and values for protection of aquatic life from chronic effects.

The basis for the first approach is that reasonable potential decisions must be performed for those effluent and environmental conditions which cause, have the reasonable potential to cause or contribute to an excursion above a water quality criterion. The consideration of effluent variability is an important component of the reasonable potential decision. Accordingly, the Great Lakes Initiative Steering Committee developed procedure 5.B.1.a through 5.B.1.c of appendix F to provide a statistical approach to better characterize the effects of effluent variability as measured by a predicted maximum effluent concentration. In the proposed rule, the estimated maximum concentration is calculated, in most applications, as an upper bound (99th percentile) of the distribution of effluent concentrations. The 99th percentile was selected as a reasonable measure of the maximum effluent concentration. Where a sufficient number of effluent measurements exist, the maximum value of all of the concentrations may be a close approximation of the 99th percentile concentration. The information is then used by the permitting authority to determine the need for a WQBEL.

The second method, which is set forth at procedure 5.B.1.d of appendix F to part 132, provides that the PEQ may be calculated as the upper 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration data. This statistical procedure is consistent with the procedure described in section 3.3 of the TSD. Procedure 5.B.1.d of appendix F specifies that a WQBEL must be established if the PEQ, as calculated under this second method, exceeds any of the preliminary effluent limitations developed in accordance with section 6.A.

The basis for procedure 5.B.1.d of appendix F to part 132 is that all effluent assessment approaches for individual pollutants have some degree of uncertainty associated with them. The more limited the amount of test data available, the larger the uncertainty and the lower the precision of the methodology for characterizing the maximum effluent concentration. Because of this uncertainty, EPA developed the guidance in the TSD to provide a statistical approach to better characterize the effects of effluent variability and reduce uncertainty in the process of deciding whether to require a WQBEL for a particular pollutant. The TSD guidance combines knowledge of effluent variability as estimated by a coefficient of variation with the uncertainty due to a limited number of

data to project an estimated maximum concentration for individual pollutants in a facility's effluent. The estimated maximum concentration is calculated as an upper bound of the expected lognormal distribution of effluent concentrations at a high confidence level. The information is then used by the permitting authority to determine the need for a WQBEL.

Procedure 5.B.1.d of appendix F to part 132 is based on the principles expressed in the TSD guidance document. Under procedure 5.B.1.d of appendix F to part 132, the PEQ is calculated by multiplying the maximum effluent concentration value by a factor which represents the uncertainty in the degree of variability in the effluent. The specific value of this factor depends upon the number of effluent concentration values and the variability of the effluent. The proposed Great Lakes Guidance provides these factors in Table 1 of procedure 6 of appendix F.

The calculation of the factors in Table 6 of procedure 6 of appendix F to part 132 has two parts. The first is characterization of the highest measured effluent concentration based on the desired confidence level. The relationship that describes this is:

$$p_n \geq (1 - \text{confidence level})^{1/n}$$

where "p_n" is the lower bound ("worst case") percentile represented by the highest concentration in the data and "n" is the number of samples.

The second part of this calculation is a relationship between the percentile described above and the selected upper bound of the lognormal effluent distribution. EPA's industrial treatment effluent database, which was used by EPA to develop and promulgate effluent guidelines, suggests that the lognormal distribution characterizes effluent concentrations well. For example, if five samples were collected (of which the highest value represents at least the 40th percentile at the upper 95 percent confidence level), the coefficient of variation is 0.6, and the desired upper bound of the effluent distribution is the 95th percentile, then the two percentiles can be related using the coefficient of variation (CV) as shown below:

$$\frac{c_{95}}{c_{40}} = \frac{\exp\left(1.645\sigma - 0.5\sigma^2\right)}{\exp\left(-0.258\sigma - 0.5\sigma^2\right)} = 2.3$$

Where $\sigma^2 = \ln(CV^2 + 1)$, and 1.645 and −0.258 are the normal distribution values for the 95th and 40th percentiles, respectively. The coefficient of variation of the effluent data is calculated as the standard deviation of the effluent data divided by the arithmetic average of the effluent data.

Although the 95th percentile represents a measure of the upper bound of an effluent distribution, the TSD states that other percentiles are acceptable provided they have been demonstrated to provide a similar estimate of effluent variability. Procedure 5.B.1.d of appendix F of the proposed Guidance sets these percentiles at the upper 95th percent confidence level and the upper bound of the 95th percentile. EPA recognizes that there is always uncertainty in making decisions based on data, and that there is a possibility of requiring a WQBEL where one may not be necessary, as well as not requiring a WQBEL where one is needed. This proposed approach minimizes the possibility of not requiring a limitation where one is actually needed by selecting the upper-bound 95 percent confidence level of the 95th percentile. EPA believes that use of the upper 95 percent confidence level of the 95th percentile effluent concentration is a reasonable mechanism to assure that the permitting authority will calculate an effluent concentration that appropriately characterizes the PEQ.

The proposed Guidance allows the permitting authority the flexibility to apply either the method for determining the PEQ set forth in procedure 5.B.1.a through 5.B.1.c of appendix F to part 132 or the statistical approach based on the TSD set forth in procedure 5.B.1.d of appendix F. The methods listed in procedures 5.B.1.a through 5.B.1.c of appendix F are more precise in one respect because the PEQ more closely reflects the duration aspect of the applicable water quality criterion than does the PEQ calculated under procedure 5.B.1.d of appendix F. For example, a preliminary wasteload allocation based on a criterion for wildlife will be calculated using a 30-day average stream flow and thereby represents the 30-day average preliminary effluent limitation necessary to achieve the water quality criterion. In this example, the methods listed in procedure 5.B.1.a through 5.B.1.c of appendix F of part 132 would compare the 99th percentile of the 30-day averages of effluent data to the monthly (30-day) average preliminary effluent limitation. The method listed in procedure 5.B.1.d of appendix F compares the 95th percentile of single day values of effluent data to the monthly preliminary effluent limitation. EPA believes, however, that either method equally satisfies the requirements of 40 CFR 122.44(d)(1)(ii) because both use valid statistical procedures to characterize effluent variability in defining a reasonable maximum effluent concentration to characterize the PEQ. The methods may result in different conclusions depending upon the number of data characterizing an effluent, but neither of the methods will always provide a more stringent basis for determining reasonable potential. The Great Lakes Initiative Steering Committee proposed both approaches in order to facilitate flexibility to the permitting authorities, but only endorsed these two particular methods in order to provide consistency on these determinations within the Great Lakes System. Accordingly, EPA is proposing to allow permitting authorities the option of using either statistical approach to determine the PEQ in order to: provide a balance between achieving the Great Lakes Critical Programs Act's goal of consistent minimum implementation procedures in the Great Lakes System and continuing to allow sufficient discretion to permitting authorities to implement water quality standards.

EPA invites comment on all elements of the procedures proposed in procedure 5.B.1 of appendix F of part 132 and any alternative procedures or requirements. In particular, EPA invites comment on: whether using the statistical approach in procedure 5.B.1.d of appendix F (which includes the specification of the 95th percent confidence level and the upper bound of the 95th percentile) is sufficient and if the specific requirements within procedure 5.B.1.a through 5.B.1.c of appendix F are useful and appropriate for the Great Lakes System; whether the 99th percentile is an appropriate estimate of the maximum effluent concentration for use in determining if a discharge will cause, has the reasonable potential to cause, or contributes to an excursion above water quality standards such that a WQBEL is required; and the appropriate of the provisions in procedure 5.B.1.a of appendix F requiring the permitting authority to determine whether the discharge will cause, has the reasonable potential to cause, or contribute to the excursion above a water quality criterion based on a single maximum reported value. In addition, EPA invites comment on alternative procedures for making decisions regarding the probability of an effluent causing an excursion above a water quality criterion.

ii. *Determining Reasonable Potential Where Ten or More Effluent Data Points are Available and the Effluent Flow Rate is Equal to or Greater than the 7-day, 10-*

year Flow Rate. Procedure 5.B.2 of appendix F the proposed Guidance establishes requirements for situations where the effluent flow rate is equal to or greater than the critical low flow of the stream (7Q10) and 10 or more effluent data points are available. In such effluent dominated discharge situations, the requirements are identical to those in procedure 5.B.1 of appendix F with two exceptions: The maximum effluent value, the 99th percentile value of daily samples and the 99th percentile value weekly and monthly averages must be compared to 50 percent of the preliminary effluent limitations based on wasteload allocations (instead of to the full 100 percent of the preliminary limitations); and use of the statistical approach contained in procedure 5.B.1.d of appendix F is precluded. Open Waters of the Great Lakes System are not considered to be effluent dominated under any circumstance because the volume of surface water is much greater than the volume of effluent.

With respect to the first difference, the proposed requirement to compare the PEQ to 50 percent of the preliminary effluent limitation will not increase the stringency of a WQBEL; instead it better ensures that a WQBEL will be included in a NPDES permit in effluent dominated situations in the Great Lakes System due to the lack of ambient dilution to compensate for the effects of high effluent concentrations. Because the procedures in procedure 5.B of appendix F are based on statistical estimates, there is a small potential for a facility to discharge pollutants at higher concentrations that would exceed a water quality criterion. One fundamental principle of the statistical methods used in procedure 5.B of appendix F is that a higher concentration is always possible although less likely to occur. This potential is offset by consideration of the available dilution in the receiving water, because the simultaneous occurrence of the high effluent concentration and low stream flow is rare. In contrast, there is little substantial ambient stream flow in streams with low dilution capacity. EPA believes that the 50 percent factor in procedure 5.B of appendix F provides a reasonable level of assurance that a WQBEL is imposed where appropriate.

With respect to the second difference, the statistical approach described in procedure 5.B.1.d of appendix F to part 132 does not provide a separate explicit mechanism to account for the need for additional assurances in low dilution streams. Rather, the approach addresses this factor implicitly in the selection of the confidence level used. In instances of low dilution streams, a permitting authority could use a higher confidence level to increase the likelihood that a WQBEL will be required and thereby provide the appropriate level of additional assurance. EPA believes that proper application of the proposed procedures under procedures 5.B.1.d and 5.B.2 of appendix F may result in the same likelihood of requiring a WQBEL. EPA is not proposing to allow use of procedure 5.B.1.d of appendix F in effluent dominated streams, however, because the TSD does not include specific guidance on how high to adjust the confidence level in these situations. EPA invites comment on whether the level of at least 50 percent of the potential limitation in a effluent dominated situation is reasonable to ensure that WQBELs are required where necessary, and whether the statistical approach in procedure 5.B.1.d of appendix F or an alternative approach based on the TSD should also be available as an option to the permitting authority.

iii. *Determining Reasonable Potential Where There is at Least One but Less than Ten Data Points Available.* Procedure 5.C of appendix F to the proposed Guidance establishes requirements for determining reasonable potential for small data sets (those with at least one, but less than 10 samples). The approach in procedure 5.C of appendix F is consistent with procedure 5.B.1.d of appendix F discussed above and is also consistent with the recommendations in Chapter 3 of the TSD. Under this provision, a maximum value is calculated from the highest value in the data set and a multiplying factor is based on the assumption that the coefficient of variation is 0.6 for all effluents. EPA believes that where there are less than 10 items of data, the uncertainty in the coefficient of variation is too large to calculate a standard deviation or mean with sufficient confidence. Based on the data in EPA's effluent guidelines database, which was used to develop and promulgate effluent guidelines for industrial wastewaters, a coefficient of variation of 0.6 typifies average effluent variability. For this reason, only one value of the coefficient of variation is assumed. If the maximum value thus calculated is greater than the preliminary effluent limitations based on the preliminary wasteload allocations, a WQBEL must be included in the permit.

EPA invites comment on all aspects of this provision, including whether a distinction should be made based on the number of representative effluent data samples, and whether 10 or less such samples is an appropriate basis for making a distinction. EPA also requests comment on establishing a coefficient of variation of 0.6 when there are fewer than 10 representative effluent data samples.

c. *Determining the Need for Water Quality-based Effluent Limitations in the Absence of Effluent Monitoring Data for a Specific Facility.* The proposed Guidance does not establish any new or specific requirements for determining the need for WQBELs in the absence of effluent data for a specific facility. In these instances, the permitting authority must continue to apply existing regulations and procedures consistent with 40 CFR 122.44(d)(1) to determine on a case-by-case basis whether WQBELs are necessary. EPA's existing guidance recommends that the regulatory authority use a variety of factors and information when determining whether or not a discharge will cause, has the reasonable potential to cause, or contributes to an excursion of a water quality standard if facility-specific effluent monitoring data are unavailable. (See TSD at pp. 50–55.) At a minimum, the proposed Guidance, consistent with existing regulations, requires the permitting authority to consider the four factors identified in 40 CFR 122.44(d)(1)(ii) in making a reasonable potential determination regardless of the availability of facility-specific effluent monitoring data.

If the permitting authority, after evaluating all available information on the facility, is not able to determine whether the discharge will cause, has the reasonable potential to cause, or contributes to an excursion above a water quality standard, existing EPA guidance provides that the authority should require whole effluent toxicity or chemical-specific effluent monitoring to acquire additional data. The permitting authority should require the monitoring prior to permit issuance, if sufficient time exists, or as a condition of the issued or reissued permit. If monitoring is required after permit issuance, the permitting authority should also include a specific reopener clause to allow for subsequent modification of the permit to include a WQBEL if the monitoring establishes that the discharge causes, has the reasonable potential to cause, or contributes to an excursion above a water quality criterion. (See TSD at p. 55)

EPA invites comments on whether existing guidance is sufficient for determining the need for WQBELs in the absence of facility-specific effluent monitoring data, or whether minimum requirements should be specified in the

final Guidance. EPA also solicits comments on any alternative procedures to make this determination in the absence of facility-specific data.

d. *Determination of Reasonable Potential for Pollutants for Which Great Lakes Tier II Values are Not Available.* Procedure 5.D of appendix F of the proposed Guidance specifies requirements for determining whether permitting authorities must generate or require permittees to generate, data sufficient to calculate Tier II values when pollutants on Table 6 are known or suspected of being discharged into the Great Lakes System, but neither Tier I criteria nor Tier II values have been derived due to a lack of toxicological data. In some cases, toxicological data for a particular pollutant may be available which meets the minimum database requirements for one of the categories of Tier I criteria or Tier II values, for example aquatic life, but not for human health and wildlife. Other cases may involve a pollutant present in the effluent for which no toxicological data exist. A preliminary assessment conducted by EPA indicates that there are data currently available to calculate Tier I or Tier II criteria/values for aquatic life, human health and wildlife for most of the pollutants in Table 6.

EPA recognizes that it would be preferable to have Tier I criteria available to compute WQBELs in all circumstances. However, the development of Tier I criteria is often costly and time-consuming. In the absence of a Tier I criterion, the permitting authority must have some mechanism with which to interpret and ensure that the narrative prohibition against the discharge of toxic substances in toxic amounts is reflected in permits (40 CFR 122.44(d)(1)(vi)).

The Steering Committee considered four options to address the discharge of pollutants in the absence of Tier I criterion: preclude discharge of the pollutant unless and until a Tier I criterion is developed; allow unregulated discharge unless and until a Tier I criterion is developed; allow permitting authorities to translate the narrative criterion into a numeric criterion on a case-by-case basis; or develop systematic methodologies for deriving numeric criteria and determining the need for a WQBEL to implement the criteria in the absence of a full database. As discussed in section II.D of the preamble above, the proposed Guidance implements the latter option—to propose the use of a Tier II methodology to derive values in the absence of Tier I criteria. Consistent with this decision, procedure 5.D of appendix F proposes a methodology for determining whether Tier II data must be generated by the permitting authority or discharging facility to determine the need for a WQBEL for a pollutant in the NPDES permit.

Procedure 5.D.1 of appendix F the proposed Guidance requires the permitting authority to use all available, relevant information including Quantitative Structure Activity Relationship (QSAR) information and other relevant toxicity information to develop "ambient screening values" for each of the following water quality criteria categories: aquatic life (acute and chronic); wildlife; and non-cancer human health for pollutants included in Table 6 of the proposed Guidance. These ambient screening values must be specified at a level which would not be expected to cause an excursion of the narrative water quality standard. Examples on development of ambient screening values are provided in "Technical Support Document: Establishment of Ambient Screening Values under the Great Lakes Water Quality Initiative", February 1993, which is available in the administrative record for this rulemaking. Copies are also available upon written request from the person listed in section XIII of this preamble.

Based on the specifics of the effluent data base and discharge situation (i.e., whether there are more or less than 10 data points for the particular pollutant in the effluent, and whether it is an effluent dominated or a non-effluent dominated receiving water), the permitting authority must apply the appropriate procedure described in procedures 5.A, 5.B or 5.C of appendix F to calculate a preliminary wasteload allocation and preliminary effluent limitation using the calculated ambient screening value. If based on this information, the permitting authority concludes the discharge will cause, has the reasonable potential to cause, or contributes to an excursion above ambient screening value, the regulatory authority must either generate or require the permittee to generate the data necessary to derive Tier II values for the protection of aquatic life, wildlife, and human health for the pollutant. Once sufficient data are generated to calculate a Tier II value, the permitting authority must follow the procedures set forth in procedures 5.A through 5.C of appendix F to determine whether a WQBEL must be incorporated into an NPDES permit based on the Tier II value.

Procedure 5.D.2 of appendix F of the proposed Guidance includes an alternative provision for existing discharges of pollutants listed in Table 6 other than those identified as bioaccumulative pollutants of concern, if data sufficient to calculate Tier I criteria and Tier II values for aquatic life are not available. In these cases, proposed procedure 5.D.2 of appendix F does not require permitting authorities to generate or have the permittee generate the data necessary to derive Tier II values for aquatic life or include pollutant-specific, aquatic life-based effluent limits in the NPDES permit for the discharge of those pollutants if the discharge is to segments where a biological assessment has demonstrated no acute or chronic effects on aquatic organisms and the whole effluent has not exhibited toxicity in accordance with the procedures in procedure 6 of appendix F. Procedure 5.D.2 of appendix F allows this exception from the procedures in proposed procedure 5.D.1 of appendix F for non-bioaccumulative chemicals of concern as defined in proposed 40 CFR 132.2.

EPA is proposing procedures 5.D.1 and 5.D.2 of appendix F to implement the existing NPDES regulation at 40 CFR 122.44(d)(1)(vi). These regulations direct permitting authorities in the absence of an applicable numeric water quality criterion, to establish effluent limitations for pollutants that cause, have the reasonable potential to cause, or contribute to an excursion of a narrative water quality criterion using one or more of the following options: calculate a site-specific numeric criterion; use EPA's water quality criteria (developed in accordance with section 304(a) of the Clean Water Act) supplemented where necessary by other relevant information; or establish effluent limitations on an indicator pollutant. Proposed procedure 5.D.1 of appendix F implements the first option by providing a mechanism to determine whether the effluent has the reasonable potential to cause or contribute to an exceedance of the Tier II values. As discussed in section II.D above, these values will serve as calculated minimum water quality criteria for an individual discharge to the Great Lakes System. The Steering Committee believed that a prescribed methodology for conducting reasonable potential determinations was necessary to improve consistent translation of narrative water quality criteria within the Great Lakes System. The proposed approach is also consistent with existing regulations which allow permitting authorities to require permittees to submit any data necessary to support permit development. If the permitting agency determines that a pollutant is or may be discharged at a level that will cause, have the reasonable potential to

cause, or contribute to an exceedance of any water quality standard including narrative criteria, it may require the submittal of data necessary to compute a WQBEL for that pollutant, including the data necessary to calculate a Tier I value. EPA invites comment on all aspects of this provision including whether permitting authorities should be allowed to use alternative procedures consistent with 40 CFR 122.44(d)(1)(vi) in interpreting a State's narrative water quality criterion for the purposes of establishing a WQBEL.

The proposed Guidance in procedure 5.D.1 of appendix F to part 132 does not require the permitting authority to estimate ambient screening values or to generate or require the generation of data sufficient to develop a Tier II value for human health based on carcinogenic effects. For such pollutants, the Steering Committee believed that permitting authorities already have sufficient information to protect human health from carcinogenic effects by applying one of the three options specified in 40 CFR 122.44(d)(1)(vi) for the purpose of determining whether a discharge has the reasonable potential to cause or contribute to an exceedance of a narrative water quality criterion for human health based on carcinogenic effects. In contrast to wildlife, aquatic life, and non-carcinogenic criteria, EPA has developed criteria pursuant to section 304(a) of the CWA or maintains information for developing a criterion to protecting human health from carcinogenic effects for all but four of the pollutants listed in Table 6: 2-chloroethyl vinyl ether, 2-chlorophenyl phenyl ether, di-n-octyl phthalate, and octachlorostyrene. EPA currently does not have information to indicate whether these pollutants have the characteristics of carcinogens, and invites comment on this.

Permitting authorities must consider all relevant information, including criteria published by EPA pursuant to 304(a), in making reasonable potential determinations under 40 CFR 122.44(d)(1)(vi). EPA believes that the above approach of using 304(a) criteria and other information available to calculate a criterion satisfies the requirements of § 122.44(d)(1)(vi) while providing flexibility to the permitting authority to establish any necessary effluent limitations to meet narrative or numeric water quality criteria and fully protect designated uses. EPA invites comment on all aspects of this provision including whether the permitting authority should be required to generate ambient screening values and if necessary, generate or have generated data sufficient to develop a Tier II value based on the protection of human health from carcinogenic effects of pollutants.

The proposed Guidance in procedure 5.D.2 of appendix F also does not require the development of a Tier II value for the protection of aquatic life (except for those pollutants which are considered to be bioaccumulative chemicals of concern) if the permittee demonstrates through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water and that the whole effluent does not exhibit acute or chronic toxicity based on the requirements in procedure 6 of appendix F. EPA has developed guidance on conducting biological assessments in Rapid Bioassessment Protocols for Use in Streams and Rivers (EPA/440/4–89/001, May 1989), which are available in the administrative record for this rulemaking. EPA believes that the results of a biological assessment in conjunction with acute and chronic toxicity tests serve as available, relevant information for the purposes of applying EPA's existing regulation at 40 CFR 122.44(d)(1)(vi)(C). This regulation allows permitting authorities, in the absence of an applicable numeric water quality criterion to establish any necessary WQBELs to control the pollutant by use of an indicator parameter. In the case of protection of aquatic life, EPA believes that whole effluent toxicity can serve as an indicator parameter in appropriate circumstances. Whole effluent toxicity measures the combined toxic effect of all chemicals in an effluent. This approach is also consistent with EPA's policy on independent application of water quality criteria discussed below because this procedure is limited to circumstances where whole effluent toxicity requirements are not exceeded, biological criteria are attained, and there are no data to develop a numeric criterion for the pollutant of concern. Because there is no analogous indicator parameter for the protection of human health and wildlife, EPA has proposed limiting application of this provision to the protection of aquatic life. EPA invites comment on all aspects of this provision including the exception from the requirement to generate data necessary to derive Tier II values for the protection of aquatic life if the permittee demonstrates that biological assessments have shown there are no acute or chronic effects on aquatic life and the whole effluent toxicity does not exhibit any acute or chronic toxicity. EPA also invites comment on the types of information that comprise a valid bioassessment, including whether minimum requirements for conducting these assessments should be specified in the final Great Lakes Guidance.

The proposed Guidance for procedure 5.D.2 of appendix F does not allow a similar exception for bioconcentratable chemicals of concern (BCCs) because the use of whole effluent toxicity as an indicator parameter may not be appropriate for these pollutants. Whole effluent toxicity measures the combined effect of all toxic chemicals in an effluent over the duration of the test. The whole effluent toxicity test methodologies published as guidance by EPA are conducted over a period of up to eight days. In contrast, the effects of bioaccumulation of a pollutant on an aquatic organism may not be observable within 30 days, and perhaps until the end of the lifetime of the organism. For this reason, EPA believes that whole effluent toxicity tests may be insufficient to identify significant toxic effects of BCCs. EPA invites comment on all aspects of this proposal including whether the exception should apply to pollutants that have been identified as BCCs.

Application of procedure 5.D.1 of appendix F of the proposed Guidance is only required for pollutants in Table 6. The basis for selecting the pollutants in Table 6 is discussed in section II of the preamble, above. EPA believes that requiring permitting authorities to generate or have permittees generate ambient screening values and potentially Tier II values for all pollutants present in or known to be discharged to the Great Lakes may be unnecessarily burdensome on regulated discharges or permitting authorities. EPA believes that limitation of procedure 5.D of appendix F to Table 6 pollutants is a reasonable means to improve uniform application of minimum permitting requirements throughout the Great Lakes System for the pollutants of most concern to EPA and the Great Lakes States within these waters. Determinations of the appropriate WQBEL for a pollutant not identified in Table 6 will continue to be made subject to the requirements in 40 CFR 122.44(d)(1)(vi) (A), (B), and (C). In applying these regulations, permitting authorities may interpret State or Tribal narrative water quality criteria by either calculating site-specific numeric criteria; applying EPA's water quality guidance under section 304(a) of the Clean Water Act, supplemented by other relevant information; or establishing an effluent limitation on an indicator parameter for the pollutant of concern.

EPA invites comment on all requirements and exceptions in procedures 5.D.1 and 5.D.2 of appendix

F including the procedure for determining whether the permitting authorities must generate or have the permittee generate the data necessary to derive Tier II values for the protection of aquatic life, wildlife, and human health for all pollutants known or suspected to be present in discharges; identification of procedures to minimize the costs of this data generation on permitting authorities and discharging facilities; and identification of procedures to minimize or eliminate possible inequities between facilities due to application of the data generated by one facility to subsequent permitting decisions regarding other dischargers.

Procedure 5.D.3 of appendix F of the proposed Guidance states that, where there is insufficient information to develop a Tier II value, nothing in procedure 5.D of appendix F precludes or denies the right of a State or Tribe to determine in the absence of the data necessary to derive a Tier I criterion or a Tier II value, that the discharge of a pollutant will cause, have the reasonable potential to cause or contribute to an excursion above the State's narrative criterion for water quality or incorporate a WQBEL for that pollutant in a NPDES permit. This provision is consistent with section 510 of the Clean Water Act which expressly retains the State's authority to adopt and enforce standards, limitations or requirements more stringent than those in effect under the Clean Water Act. Finally, proposed procedure 5.D.4 of appendix F clarifies that if the permitting authority develops a WQBEL pursuant to procedure 5.D.3 of appendix F under other more stringent authority, it is not obligated to generate or require the permittee to generate the data necessary to derive a Tier II value for that pollutant. When a permitting authority develops a WQBEL, the WQBEL must achieve State water quality standards including both numeric and narrative water quality criteria as required by 40 CFR 122.44(d)(1)(vii). As previously discussed in the preamble, Tier II criteria are the permitting authority's interpretation of narrative water quality criteria. Therefore, if a permitting authority establishes a WQBEL under other more stringent authority when a WQBEL is not mandated by procedure 5 of appendix F, it is not also required to apply the Tier II methodologies to interpret that narrative water quality criterion.

e. *Consideration of Intake Water Pollutants When Determining Reasonable Potential*—i. *Introduction.* The proposed Guidance in appendix F, procedure 5.A. through D., provides procedures for permitting authorities to determine if a discharge causes, has the reasonable potential to cause or contributes to an excursion above a State or Tribal numeric or narrative water quality criterion. These proposed procedures require the permit authority to establish water quality-based effluent limitations upon determination that a pollutant is or may be discharged at sufficient levels to cause, have the reasonable potential to cause or contribute to an excursion above any Tier I criterion or Tier II value.

The proposed procedures for conducting reasonable potential determinations in 5.A. through 5.D. do not provide special considerations for pollutants contained in a facility's intake water. In some situations, the sole or primary origin of a pollutant in a discharge may be the intake water for a facility. For example, the origin of many pollutants in once through cooling water is the water body where the facility obtains the water rather than a facility wastestream.

Procedure 5.E. of appendix F of the proposed Guidance provides a separate mechanism for permitting authorities to consider the presence of intake water pollutants in a facility's discharge when determining the necessity for WQBELs. Procedure 5.E. of appendix F would allow the permitting authority to determine that the return of identified intake water pollutants to the same body of water under specified circumstances does not have the reasonable potential to cause or contribute to an exceedance of water quality standards without application of the reasonable potential procedures set forth in procedure 5.A. through 5.D of appendix F. Based on this determination, the permitting authority would not be required to establish WQBELs for the identified intake water pollutants. This procedure would apply to facilities that return unaltered intake water pollutants to the same body of water without increasing the mass loading rate or concentration of the pollutant at the edge of any available mixing zone, and that do not discharge the intake water pollutants at a time or location that would cause adverse water quality effects to occur that would not have occurred if the pollutants were left in place.

The proposed procedure would supplement existing mechanisms to modify technology-based effluent limitations to reflect intake water pollutants, and to derive appropriate WQBELs for discharges to water that exceed water quality criteria. These mechanisms include Total Maximum Daily Loads (TMDLs), temporary variances from water quality standards, modifications to designate uses, and site-specific modifications to criteria. Application of these existing mechanisms to address intake water pollutants is discussed below.

In addition to the proposed procedure 5.E of appendix F to part 132, EPA considered four alternative options for addressing intake water pollutants. Each of these options is discussed in more detail in subsection e.iv below.

Option 1. Option 1 reflects the current national approach. While EPA's existing regulations do not provide for a special credit for pollutants present in a facility's intake water in the calculation of WQBELs, several mechanisms are available that may result in an adjustment in a WQBEL to reflect the presence of intake water pollutants (e.g. TMDLs, temporary variances from water quality standards, and changes in the designated use of the water body or site-specific criteria modifications). Option 1 would limit the regulatory procedures to address intake water pollutants to these existing mechanisms.

Option 2. In addition to allowing the use of the procedures in Option 1, Option 2 would allow a permitting authority to modify WQBELs directly to provide a full or partial credit for intake water pollutants when the pollutants are discharged to the same water body as the intake water. A specified level of credit would be allowed under this approach even when the facility contributes an additional amount of the intake water pollutant from its process waste stream.

Option 3. This option is similar to Option 3, but it would also allow the permitting authority to modify WQBELs when the source of the intake water is different from the receiving water.

Option 4. This option is the initial procedure developed by the Great Lakes Technical Work Group. It is a combination of Options 2 and 3 and would provide a direct mechanism for reflecting a credit for pollutants in a facility's intake water under specified circumstances.

Although the Great Lakes Steering Committee did not adopt the procedure drafted by the Technical Work Group (Option 4), it believed that the draft Great Lakes Guidance should include a provision addressing the discharge of intake water pollutants to the Great Lakes System. Accordingly, EPA agreed to convene a separate workgroup to evaluate the extent to which permitting authorities may consider the presence of intake water pollutants during the development of WQBELs. Proposed procedure 5.E of appendix F reflects the efforts of this workgroup. EPA requests comment on all aspects of this subject,

including proposed procedure 5.E, all issues raised in the preamble discussion below, and any suggested alternative requirements or combinations of requirements to address the subject and issues in the final rule.

ii. *Current National Approach*—(A) *Net/Gross Credits for Technology-based Limits.* EPA's NPDES permitting regulation at 40 CFR 122.45(g) currently provides a mechanism for adjusting treatment technology-based effluent limitations to reflect credit for pollutants in a discharger's intake water. The regulation specifies the circumstances under which EPA will adjust a facility's technology-based effluent limitation to account for the presence of pollutants in a discharger's intake water. The regulation provides that technology-based limitations shall be adjusted where the applicable effluent limitations guidelines direct limitations be applied on a net basis or where the discharger demonstrates that the presence of intake water pollutants prevents compliance with the applicable technology-based limitations despite proper installation and operation of the treatment systems. The regulation also identifies four specific conditions restricting the use of net credits:

(1) The regulation precludes the use of net credits for generic or indicator pollutants unless the permittee demonstrates that the constituents of the generic measure in the effluent and influent are substantially similar or unless appropriate additional limits are placed on process water pollutants.

(2) Credit may be granted only to the extent necessary to meet the applicable technology-based limitation, up to a maximum value equal to the influent value.

(3) Credit is generally limited to discharges to the same body of water from which the intake water is drawn although the Director may waive this requirement if no environmental degradation will result.

(4) Credit is precluded for return of materials generated from the treatment of intake water (e.g., raw water clarifier sludge).

The provision granting credit only to the extent necessary to achieve a technology-based limitation assures that a discharger uses the appropriate technology-based level of treatment (e.g. BPT/BAT/BCT) in removing pollutants that originate from the discharger's facility. This provision in essence assures the proper operation of treatment technology.

In the promulgation of this 40 CFR 122.45(g), EPA declined to develop a similar mechanism to adjust water quality-based effluent limitations to reflect credit for intake water pollutants. EPA explained that "[t]he Clean Water Act's requirement to protect and enhance water quality is not conditioned on factors such as intake water quality and it would be inappropriate for EPA to impose such a condition. Eligibility for a net credit under these [technology-based] regulations does not imply any right to violate water quality standards." (49 FR 37998, 38027 (September 26, 1984)). EPA recognized the complexity of water quality-based permitting, however, and indicated that permit writers may take the presence of intake water pollutants into account, as appropriate, in individual permitting decisions. In all cases, EPA noted that permit limits "must be adequate to meet the water quality objectives of the Clean Water Act when considered along with control requirements for other discharges to the stream." (49 FR 38027 (September 26, 1984)). The existing mechanisms for simultaneously considering control requirements for all dischargers to a single body of water are total maximum daily loads (TMDLs) and NPDES permits written to implement these TMDLs. The use of TMDLs to address intake water pollutants is discussed further below.

(B) *Consideration of Intake Water Pollutants for Water Quality-based Limits.* Existing National regulations and guidance allow the permitting authority to utilize four mechanisms to determine appropriate WQBELs when the receiving water exceeds a water quality criterion. These mechanisms which are discussed below are total maximum daily loads, variances, removal of non-existing uses, and site-specific modifications to water quality criteria.

In addition to mechanisms, facilities with intake water that contain pollutants at concentrations above water quality criteria may be able to reduce the level of these pollutants through pollution prevention measures. Although pollution prevention is a voluntary action under the existing NPDES permit program, pollution prevention techniques can help reduce the amount of a pollutant in an intake water and therefore reduce the amount of a pollutant that a facility may need to discharge. For example, a facility using groundwater contaminated with DDT may be able to use an alternative intake water source, such as a municipal or surface water supply, that does not contain this pollutant. Substitution of an alternative source of intake water may remove the necessity for or decrease the stringency of any WQBEL and improve the quality of the receiving water body.

Another type of pollution prevention involves source reduction within the facility. One example of this approach is a waste paper facility that discharges PCBs (that are present in a process waste stream and the intake water source) to a receiving body of water that already exceeds the criterion for PCBs. By switching to a different source of waste paper, one with less PCBs in the ink, the facility may be able to meets its WQBEL without having to install additional treatment technology. This type of source reduction is also beneficial to the environment because the effluent would contain less PCBs, a toxic bioaccumulative pollutant of concern.

A second example of source reduction within a facility is a utility with an effluent containing copper due at least in part to corrosion from its copper pipes at a level that would have a reasonable potential to cause or contribute to an exceedance of the criterion for copper. The facility could increase the hardness of the water that passes through the copper pipes, thereby reducing the amount of copper in the effluent from corrosion. The utility may then be able to comply with any necessary WQBEL for copper through this source reduction measure.

In addition to pollution prevention efforts conducted by the facility, regulatory authorities may utilize four mechanisms to determine appropriate WQBELs when the receiving water exceeds a water quality criterion. Regulatory authorities may:

(1) Develop an appropriate waste load allocation for the discharger through a TMDL that is designed to lead to attainment of water quality standards, pursuant to State requirements consistent with 40 CFR Part 130;

(2) Grant a temporary variance from water quality standards to an individual discharger, pursuant to State requirements consistent with 40 CFR 131.10 and 131.13;

(3) Remove a non-existing designated use where unattainable and designate a less stringent use and corresponding criteria to protect existing and/or attainable uses pursuant to State requirements consistent with 40 CFR 131.10; or

(4) Develop a site-specific criterion for the water segment pursuant to State requirements consistent with 40 CFR 131.11(b).

If the permitting authority utilizes a TMDL, a WQBEL for the pollutant may be less stringent or unnecessary if the TMDL provides for the attainment of water quality standards through load

reductions from other point or nonpoint sources. If the permitting authority utilizes a variance from water quality standards, a modified designated use or a site-specific criterion, a WQBEL for the pollutant may be less stringent than the WQBEL necessary to meet the original criterion or unnecessary to reflect the temporary variance or change in the State water quality standards.

As discussed below, application of one or more of these mechanisms may be appropriate to reflect the presence of intake water pollutants above State water quality criteria. All four existing mechanisms can be applied whether the discharge is to a body of water meeting or exceeding water quality standards, and regardless of the intake water quality. EPA offers this variety of mechanisms because decisions whether a WQBEL is necessary, and if so, establishment of the appropriate level, should be made on a case-by-case basis. In some situations, one of these mechanisms will provide a clear vehicle for establishing appropriate WQBELs when background concentrations exceed water quality standards. For example, if the sole cause for non-attainment of water quality criteria is that the criteria do not reflect local unique conditions, then a site-specific criterion modification is the appropriate mechanism. In other cases, compliance with water quality standards may be possible only with a combination of mechanisms. Additional discussion of these mechanisms is also contained in the following preamble sections: section VIII.D., Total Maximum Daily Load, Wasteload Allocations Procedures; section VIII.C, Variances from Water Quality Standards; and section VIII.B, Site-Specific Modifications to Criteria/Values.

(1) *TMDLs.* Section 303(d) of the CWA and 40 CFR 130.7 require States to develop TMDLs for waters that are not expected to meet applicable water quality standards after existing pollution control requirements (including technology-based controls) are in place. A TMDL establishes the total allowable pollutant load that can exist in a body of water while maintaining water quality standards; the TMDL allocates this allowable load among all pollutant sources. A TMDL is the sum of the waste load allocations (point source load allocations), load allocations (nonpoint source load allocations), a margin of safety to account for any uncertainties, and any reserve capacity for future growth.

Pollutants in a facility's intake water may originate from upstream point sources or nonpoint sources (including natural background). If the TMDL provides for the attainment of water quality standards through load reductions from sources other than the facility's discharge, a WQBEL may be unnecessary for the facility's discharge of intake water pollutants.

EPA interprets section 303(d) of the Clean Water Act as requiring States to develop TMDLs and begin requiring pollution control even in the absence of complete information. EPA's April 1991, Guidance for Water Quality-based Decisions: The TMDL Process, which is available in the administrative record for this rulemaking, encourages a phased approach to TMDL development in situations where data are incomplete or modelling is difficult. Under the phased approach, a TMDL is developed using all available information, professional judgment, and a margin of safety to account for uncertainties. The TMDL includes a monitoring plan and a schedule for assessing the attainment of water quality standards after implementation of the pollution controls. The monitoring program acts as a safeguard and, if water quality standards are not attained after implementation of the TMDL or it is determined that allocations could be larger without exceeding standards, the data obtained through the monitoring program can be used to develop a revised TMDL.

Phased TMDLs can be effectively used to address the presence of intake water pollutants and to remedy violations of existing water quality standards by fairly allocating the burden of reducing undesirable discharges among all sources. An example where a phased TMDL may be appropriate to address intake water pollutants is a facility that discharges mercury attributed to both its intake water and process waste stream to a water body that exceeds the water quality criterion for mercury. The sources of ambient mercury in the intake water include upstream permitted point source dischargers, and releases from contaminated sediments. A phased TMDL could reflect projected reductions in mercury loads from a required or scheduled sediment remediation project and from reductions in discharges from upstream point sources. Under these circumstances, the permitting authority may determine that a WQBEL for mercury for this facility is unnecessary or should be less stringent to reflect the projected load reductions. Additional load reductions by this facility beyond the capability of the required treatment technology would not be necessary if attainment of standards could be achieved by these other measures. The TMDL would identify the implementation plan for load reductions, document that these actions are expected to attain water quality standards based on predictive water quality models, and in the case of a phased TMDL, describe the plan for implementation, monitoring, and assessing whether standards are in fact attained after implementation.

Elimination or modification of WQBELs based on a phased TMDL may be available to dischargers whose intake water contains pollutants for which the water quality criteria are exceeded. The phased approach for TMDLs is discussed further in section VIII.D of the preamble.

(2) *Variances from Water Quality Standards.* Second, States may currently grant a temporary variance from water quality standards to an individual discharger pursuant to State requirements consistent with 40 CFR 131.10 and 131.13 and National guidance. The intent of a variance from water quality standards is to provide a mechanism by which a permit can be written to meet an interim standard in situations where short-term compliance with the underlying non-attained water quality standard is demonstrated not to be feasible because of one or more of the reasons listed in 40 CFR 131.10(g). In addition, a variance from water quality standards maintains the designated use as a goal to be achieved in the long-term instead of removing a use where the current limiting conditions are considered ultimately correctable. Procedure 2.C of appendix F of the proposed Guidance would allow the Great Lakes States to continue to grant variances for the same reasons recognized under the National program.

There are several conditions under which variances from water quality standards may be granted that are appropriate to issues of background water quality. For example, a State could allow a variance under 40 CFR 131.10(g)(1) and proposed procedure 2.C.1 of appendix F when "naturally occurring pollutant concentrations prevent the attainment of the use"; 40 CFR 131.10(g)(3) and proposed procedure 2.C.3 of appendix F when "human caused conditions or sources of pollution prevent the attainment of the use and cannot be remedied or would cause more environmental damage to correct than to leave in place"; or 40 CFR 131.10(g)(6) and proposed procedure 2.C.6 of appendix F when "controls more stringent than those required by sections 301(b) and 306 of the CWA would result in substantial and widespread economic and social impact." Such variances may be available to dischargers whose intake

water contains pollutants for which the water quality criteria are exceeded.

An example where a variance may be appropriate is a situation where a stream bed contains sediments upstream of a permitted discharger contaminated by a specified pollutant. Resuspension of the contaminated sediments has resulted in an exceedance of the water quality criterion for the pollutant in-stream. Removing the sediments may cause more environmental damage than to leave them in place for future remediation. The permitted facility discharges effluent containing this pollutant that is present in both the intake water and in its process waste stream. By granting a variance and calculating an interim water quality criterion based on the current condition of the water body reflecting the background source of the pollutant, a WQBEL for this discharge would be established to meet this interim water quality criterion. This approach should still result in further improvement towards attaining the existing water quality standards.

Another example where a variance may be appropriate is a utility company with intake water containing levels of copper that exceed the applicable water quality criterion. The facility's discharge also contains a small amount of copper due to corrosion of the facility's pipes. Adding a treatment system to remove the copper in the discharge to a level necessary to assure attainment of the designated use or switching to an alternative source of intake water might increase facility costs substantially. If those costs would result in large increases in utility rates in the area, they could be considered to cause a substantial and widespread social and economic impact. By granting a variance from water quality standards that establishes an interim criterion for copper that accounts for the background level and the level of incidental removal obtained by the discharger's proposed or existing treatment systems, an NPDES permit could be written which ensures compliance with the interim criterion without requiring additional treatment by the facility.

Another example where a variance may be appropriate is a regional public water supply with an intake water that contains an ubiquitous pollutant which is found in almost all water bodies in a watershed at about the same concentration due to watershed-wide contributions from nonpoint sources, and for which the concentrations exceed the applicable water quality criterion. Adding a treatment system to remove the pollutant in the discharge to a level necessary to assure attainment of the designated use might result in large increases in utility rates in the area and could be considered to cause a substantial and widespread social and economic impact. Also, switching to an alternative source of intake water may not be practical because the pollutant exists throughout the basin due to nonpoint sources. By granting a variance from water quality standards that establishes an interim criterion for the pollutant that accounts for the background level and the level of incidental removal obtained by the discharger's proposed or existing treatment systems, an NPDES permit could be written which ensures compliance with the interim criterion without requiring additional treatment by the facility.

The use of variances to address discharges to water bodies exceeding water quality standards within the Great Lakes System is discussed further in section VIII.C of the preamble.

(3) *Modifications to Designated Uses.* Third, States may currently remove a non-existing designated use where unattainable and adopt less stringent criteria to protect existing and/or attainable uses pursuant to State requirements consistent with 40 CFR Part 131.10. This regulatory provision is appropriate to address situations where the water quality standards for a water body are not attainable in the future. A State may remove a designated use that is not an existing use if it can demonstrate that attaining the use is not feasible due to one or more of the six factors in 40 CFR 131.10(g). These are the same factors for granting a variance identified in EPA's existing guidance and in procedure 2 of appendix F of the proposed rule. A State is required to conduct a use attainability analysis in accordance with 40 CFR 131.10 if the revised uses are less than the fishable/swimmable goals of the CWA specified in section 101(a) or if the State adopts subcategories of uses specified in section 101(a) which require less stringent criteria.

The proposed Guidance requires States to adopt specific numeric criteria for the protection of human health that are equal to or more stringent than those set forth in section 132.3, Table 3. All of the criteria are calculated assuming that the waters are used for fishing. However, the Table includes both cancer and non-cancer criteria that differ depending on whether the State waters are designated for (or have existing) drinking water uses. For many pollutants the criteria are more stringent for waters with drinking water uses. Thus, if States remove a non-existing drinking water designated use for a water body, the human health criteria that would be required under the proposed Guidance would be less stringent for many chemicals than it would be otherwise. Similar relief is possible when the proposed human health methodology is used to derive criteria or values for pollutants other than those listed in Table 3. Modifications of designated uses for aquatic life and wildlife protection would have no impact under the proposed Guidance because the criteria set forth in Tables 1, 2 and 4, and the criteria and values developed pursuant to methodologies referenced in § 132.4, apply to waters of the Great Lakes basin regardless of designated use. Site specific modifications to acute and chronic aquatic life criteria are available in procedure 1 of appendix F of the proposed Guidance in those instances where local water chemistry alters the biological availability or toxicity of a pollutant or where the sensitivity of the local aquatic organisms differ significantly from the species used to develop the criteria. In addition, site specific modifications to chronic aquatic life criteria are available in procedure 1 of appendix F of the proposed Guidance to reflect local physical and hydrological conditions.

(4) *Site-Specific Modifications to Criteria.* Fourth, a State or permittee may develop site-specific criteria for a water body. Site-specific modifications need to be submitted to EPA for approval or disapproval pursuant to CWA section 303(c)(2). EPA guidance on development of site-specific aquatic life criteria is contained in Chapter 4 of the U.S. EPA Water Quality Standards Handbook, which is available in the administrative record for this rulemaking. The guidance provides for site-specific adjustment of criteria when (1) site water has different chemical characteristics of water than the water used in studies upon which the criteria are based, where the differences have been demonstrated to affect the biological availability and/or toxicity of a pollutant, or (2) the sensitivity of local aquatic organisms (i.e. those that would live in the water absent human-induced pollution) differs significantly from the sensitivity of species tested in developing the criterion.

Under the proposed Guidance, site-specific modifications may result in either more or less stringent acute and chronic aquatic life criteria, but may result only in more stringent wildlife or human health criteria. Accordingly, such modifications may be available to provide relief in situations involving pollutants in intake waters where the most stringent criterion for a pollutant

of concern is an acute or chronic aquatic life criterion. The bases a State may use for justifying such less stringent criteria are discussed in section VIII.A of the preamble.

(5) *Additional Examples of Application of Existing Mechanisms.* Another example of the application of existing mechanisms to address intake water pollutants is a facility located on a river that uses the river as both its intake water source and receiving water for the discharge. Contaminated sediments amassed behind a dam on the river are contributing to polynuclear aromatic hydrocarbon (PAH) concentrations that currently exceed the State water quality criterion for PAHs. The facility discharge includes PAHs from both its process waste stream and from the intake water.

Under Option 1, the permitting authority would apply proposed procedures 5.A through 5.D of appendix F to determine whether the discharge has the reasonable potential to cause or contribute to the exceedance of water quality standards. If reasonable potential is demonstrated, the permitting authority would need to determine an appropriate WQBEL for PAHs based on the existing State water quality standards for this discharge to a non-attainment water. At least two exceptions to a WQBEL based on existing State criteria, however, may be available for this scenario for discharges to the Great Lakes System under the proposed Guidance. First, if the contaminated sediments could not be remedied in the near term or would cause more environmental damage to correct than to leave in place, the facility could request a temporary variance from the water quality criterion under proposed procedure 2 of appendix F of the proposed Guidance. This would result in the facility receiving a less stringent or no WQBEL for PAHs in the discharge.

Second, if remediation of the contaminated sediments was technologically feasible, the appropriate authority could develop a phased TMDL under proposed procedure 3 of appendix F of the proposed Guidance based on available information, professional judgment, and a margin of safety to account for uncertainties. Based on documentation of a required implementation plan for remediation of the contaminated sediments, the TMDL could allot a larger wasteload allocation to the facility to correspond to the projected loading reductions to be attained in a reasonable time period from sediment release. This would result in either a less stringent or no WQBEL for PAHs for the facility.

Additional examples of the use of TMDLs, variances from standards, and site-specific criteria modifications to address pollutants from intake waters exceeding water quality criteria are contained in the discussion of those procedures above.

iii. *Proposed Guidance.* Procedure 5.E of appendix F of the proposed Guidance provides a new procedure for considering the presence of intake water pollutants in water quality-based permitting decisions in addition to the available mechanisms described above. The proposed Guidance would allow the permitting authority to determine that there is no reasonable potential for the discharge of a particular intake water pollutant to cause or contribute to an excursion above a narrative or numeric water quality criterion without application of the procedures in procedure 5.A through 5.D of appendix F based on the permittee's demonstration of specified conditions. If these conditions are demonstrated, the permitting authority would not be required to include a WQBEL for the pollutant in the facility's permit. If these conditions are not satisfied, the permitting authority would follow the reasonable potential procedures in procedure 5.A through 5.D of appendix F to determine whether a WQBEL is necessary for these discharges.

Proposed procedure 5.E of appendix F was developed by a joint EPA and State work group in 1992. Upon initial review of the draft provision addressing intake water pollutants developed by the Great Lakes Technical Work Group (Option 4 in the preamble), EPA was concerned that the provision may be inconsistent with EPA's regulations and interpretation of the CWA. These concerns are expressed in the discussion of Options 2, 3, and 4 below. EPA formed a joint EPA and State work group comprised of all ten EPA regional offices, EPA's national office, and five States to review the existing national regulations to determine whether an alternative option should be developed to address intake water pollutants. This work group identified and evaluated the relevant technical factors and issues, and drafted a procedure for determining whether a discharge of intake water pollutants would cause or contribute to excursions above numeric or narrative water quality criteria. Proposed procedure 5.E of appendix F reflects the efforts of that work group.

Proposed procedure 5.E. of appendix F would provide a separate mechanism for determining whether water quality-based effluent limitations are necessary for facilities that return unaltered intake water pollutants to the source of the intake water. EPA believes that the return of intake water pollutants to the waters of the United States after removal and use of the water by industrial facilities is an addition of pollutants subject to regulation under section 402 of the CWA. Once the water is removed for use in industrial operations, it has lost its status as waters of the United States and the discharge must be governed by appropriate conditions in an NPDES permit, including any limitations necessary to meet applicable water quality standards. (See, *NWF* v. *Consumers Power,* 862 F.2d 580, 589 (6th Cir. 1988), distinguishing impoundment and subsequent release of water at hydroelectric facilities which generally is not subject to section 402 regulation from "the diversion of waters of the United States by industrial operations for cooling purposes in which the water loses its status as water of the United States". See also, *NWF, Id.* at 585, distinguishing impoundment and subsequent release of water at hydroelectric facilities from discharges from seafood processors which remove fish from the waters of the United States for processing and discharge the remaining fish materials back to the waters of the U.S.; *Association of Pacific Fisheries* v. *EPA,* 615 F.2d 794 (9th Cir. 1980), affirming in part, EPA's national effluent guideline regulating discharges from seafood processing facilities; *Rybachek* v. *EPA,* 904 F. 2d 1276, 1285 (9th Cir. 1990), holding that resuspension or redepositing of materials discharged in placer mining, including materials originally from the streambed or adjoining banks, is the addition of pollutants; *United States* v. *M.C.C. of Florida, Inc., 772 F. 2d 1501, 1506 (11th Cir. 1985), holding that* redepositing of vegetation and sediment by propellers of tugboat onto adjacent sea grass beds is the addition of pollutants; *Avoyelles Sportsmen's League* v. *Marsh,* 715 F. 2d 897, 923–924 (5th Cir. 1983), holding that redepositing of materials taken from wetlands during land clearing activity is the addition of pollutants.)

Industrial representatives have previously argued that the discharge of intake water pollutants is not an addition of pollutants subject to regulation under the CWA and, therefore, that EPA should provide for simple subtraction of all amounts of intake pollutants from any technology-based effluent standards. (49 FR 38025–38027, September 26, 1984; See also, *Appalachian Power* v. *Train,* 545 F.2d 1351, 1377 (4th Cir. 1977); *American Iron and Steel Institute* v. *EPA,* 526 F.2d 1027 (3rd Cir. 1975)). EPA rejected these

arguments in the preamble supporting the 1984 net-gross regulation for technology-based limitations reasoning that such subtraction was inappropriate because treatment systems typically reduce pollutants to a given level despite variations in influent concentrations. EPA asserted that to grant an absolute credit under these circumstances:

> may give an unfair advantage to facilities with measurable levels of pollutants in their intake waters. Such facilities, by relying on intake credits, could "comply" with effluent limitations by utilizing a lower level of treatment than their competitors on cleaner streams—frequently a far lower level of treatment than that designated by EPA as BAT. (49 FR at 38026).

Based on this reasoning, the final regulation at 40 CFR 122.45(g) limited the availability of credits for intake water pollutants in calculating technology-based limitations to the specified conditions discussed in subsection 5.E.2.e.ii.(A) above, including that credit could only be granted to the extent necessary to meet the applicable technology-based limit, up to a maximum value equal to the influent value. This requirement generally precludes an "absolute" credit equal to the amount of pollutants in the intake water to the extent that these pollutants can be removed through proper operation and maintenance of the facility's control systems. EPA also indicated in the supporting preamble that such limitations on the availability of net credits for calculating technology-based limits comported with the Fourth Circuit's decision in *Appalachian Power. Id.*, at 38027. (See also, *American Petroleum Institute* v. *EPA*, 540 F.2d 1023 (10th Cir. 1976) and *Hooker Chemicals and Plastics* v. *Train*, 537 F.2d 620 (2d Cir. 1976) holding that EPA's 1975 net-gross regulation was a satisfactory answer to the argument that all technology-based effluent limitations must be expressed in net terms). Although challenges were also filed to the 1984 regulation governing intake credits for technology-based effluent limitations, the United States Court of Appeals for the District of Columbia Circuit held that the rule was not ripe for review until applied in a specific permit. (*NRDC* v. *EPA*, 859 F.2d 156, 204–205 (D.C. Cir. 1988).

Reliance on these decisions by industry representatives to support an argument that EPA is required to allow net credits in the calculation of WQBELs is also misplaced because of the fundamental differences between technology-based and water quality-based effluent limitations under the CWA. The authority for establishing the existing intake regulation is derived generally from EPA's authority to establish technology-based effluent limits under sections 301, 304 and 306 of the CWA. Under those sections, EPA must develop increasingly stringent effluent limitations based on the improving technological capabilities of treatment plants and economic achievability. In developing a mechanism for net credits in the calculation of technology-based limitations, EPA recognized that the presence of pollutants in intake water may prevent a facility in some circumstances from obtaining the statutorily mandated level of pollutant removal (e.g. BPT, BAT or BCT). Under those circumstances, the failure to allow adjustment of technology-based limits to reflect the pollutants would in effect impose a higher level of control than statutorily required. As discussed further above, three Circuits have indicated that the 1975 net credit regulation provides an adequate mechanism for addressing this problem in the calculation of technology-based limits.

The authority to establish WQBELs, in contrast, is derived primarily from section 301(b)(1)(C) of the CWA. This section requires application of any more stringent limitation necessary to meet water quality standards after application of technology-based controls. Legislative history and judicial decisions have emphasized the fundamental differences and purposes of these two effluent limitations. (See, House Debate H.R. 11896 (March 27, 1972, Leg. Hist. at 375, 379). See also, *NRDC* v. *EPA*, 859 F.2d 156, 210 (D.C. Cir. 1988), holding that the CWA by virtue of the important differences between technology-based and water quality-based standards, does not require EPA to provide for an upset defense to water quality-based permit limitations violations and remanding for further proceedings).

EPA has gained extensive technical expertise in the two decades of NPDES permitting on the nature of pollutants and the effects of pollutants on waters on the United States. Based on this experience, EPA believes that determinations whether a discharge of intake water pollutants should be limited by a WQBEL and, if so, the scope of such limitations, must be determined after consideration of site-specific factors. These factors include consideration of the applicable water quality criteria, the quality of the receiving water in relation to these criteria, additional pollutant loadings from other point and non-point sources, and evaluation of the facility's effluent. As discussed further below, the effect of the discharge of intake water pollutants may also vary substantially depending on the location of the outfall in relation to the intake point, the time interval between intake and discharge of the water, alterations of the pollutant by the waste water treatment process, or synergistic or additive interactions between the intake water and other waste water pollutants.

Additionally, EPA recognizes that impairment of water quality is determined not only by the magnitude of a pollutant, but also by its chemical nature in the environment. For example, 100 µg/l of lead in a dissolved form in a river would likely cause a fish kill whereas it may not if the lead was tightly bound to suspended solids. With regards to pollutants in a facility's intake water, removal of 10 kg/day of non-bioavailable lead and replacement with 10 kg/day of bioavailable lead would place an additional stress upon the receiving water.

EPA believes that proposed procedure 5.E of appendix F would provide a reasonable mechanism for evaluating the site-specific water quality effects from the discharge of intake water pollutants. This procedure would allow permitting authorities to conclude that the return of unaltered intake water pollutants to the same body of water under identified circumstances does not have the reasonable potential to cause or contribute to an exceedance of water quality standards. Under this procedure, permitting authorities would not be required to apply the reasonable potential determination procedures set forth in procedure 5.A. through 5.D of appendix F or to establish a WQBEL to control the discharge of an intake water pollutant.

Proposed procedure 5.E of appendix F would be applied on a pollutant-by-pollutant and outfall-by-outfall basis. For example, if a facility takes in water containing lead and copper, procedure 5.E of appendix F would be available for the parameter lead, even if the facility contributes additional copper to its discharge from a waste stream or other source but does not contribute additional lead or alter the lead in the intake water. The determination whether a WQBEL would be necessary for copper under these circumstances would be made based on the procedures in procedure 5.A through 5.D of appendix F.

An example of the application of proposed procedure 5.E of appendix F is for a steam electric power plant with once-through cooling water. In this example, a steam electric facility is located downstream from a shoe manufacturer that discharges bis(2-

ethylhexyl)phthalate. The steam electric plant's intake water contains this pollutant in a concentration that exceeds the State water quality criterion. The facility is able to demonstrate that it does not contribute an additional amount of this pollutant from any source other than the intake water; that the pollutant is not concentrated at the edge of any mixing zone or adversely altered in the process of once-through cooling prior to its return to the same body of water; and that the timing and location of the effluent discharge does not cause adverse impacts to occur that would not occur if the pollutant was left instream. This steam electric power plant would qualify for a determination of no reasonable potential for bis(2-ethylhexyl)phthalate and would not need a WQBEL for this pollutant.

The permittee would be eligible for the reasonable potential procedure in proposed procedure 5.E of appendix F upon demonstration of five conditions. First, the permittee would need to demonstrate that it withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made. Facilities with multiple sources of intake water that are not commingled but discharged from separate outfalls would be eligible for this new procedure for any outfall(s) where 100 percent of the intake water is drawn from the same body of water into which the discharge is made. Facilities with co-mingled intake waters would also be eligible if they could demonstrate that the pollutant of concern is not present in intake water withdrawn from any other body of water. If the discharge from an outfall includes intake water containing the pollutant of concern from sources other than the receiving water, the permitting authority would instead need to make a determination of reasonable potential based on the procedures in procedures 5.A through 5.D of appendix F.

EPA believes that restriction of proposed procedure 5.E of appendix F to dischargers to the same body of water is appropriate to ensure consistency with the structure and function of State or Tribal water quality standards. Water quality standards include State designated uses and both narrative and numeric criteria to ensure protection of those uses for a specified water body or segment. 40 CFR 131.3(i). The failure to restrict this provision to discharges to the same body of water as the intake source would allow the addition of pollutants to a separate water body or segment for the first time without determining whether the new discharge has the reasonable potential to cause or contribute to an exceedance of applicable water quality criteria based on consideration of site-specific factors including the condition of the receiving water and contributions by other point or non-point source discharges.

The restriction of proposed procedure 5.E of appendix F to the same body of water is also consistent with the general preclusion of credits for the discharge of intake water pollutants to different bodies of water when deriving technology-based limitations under 40 CFR 122.45(g). As discussed further above, this technology-based regulation does not affect the discharger's obligation to comply with any more stringent limitations necessary to meet the applicable water quality standards. The regulation initially precluded credit for intake water pollutants in deriving technology-based limitations under all circumstances unless the permittee demonstrated that the intake water was drawn from the same body of water into which the discharge was made (45 FR 33451, section 122.63(h)(1) (May 19, 1980)). In 1982, EPA proposed to delete the same body of water restriction for calculating technology-based limitations. Industry commenters supported this proposal arguing that limitations to implement water quality standards would be sufficient to protect receiving waters. Commenters opposed to this proposal argued that limitations based on water quality standards alone were inadequate because States had not developed numeric water quality criteria for many toxic pollutants (47 FR 52081). In the final rule, EPA agreed with commenters that many States had not yet developed specific criteria for many toxic pollutants and, therefore, "meeting water quality standards [was] not alone a sufficient condition for this waiver." Based on this concern, EPA retained the general preclusion of credit for intake water pollutants from sources other than the receiving water in the calculation of technology-based limitations, but allowed the Director to waive the same body of water requirement for those limitations if no environmental degradation would result from the discharge. (49 FR 38026 (September 26, 1984)).

EPA invites comment on all aspects of this condition including whether the final Guidance should define the phrase "same body of water" or allow permitting authorities discretion to interpret this phrase on a case-by-case basis. As discussed further above, the purpose of restricting the application of proposed procedure 5.E of appendix F to dischargers to the same body of water is to ensure adequate evaluation of the applicable water quality standards for the receiving water and consideration of the presence and amounts of other sources of the pollutant. One option under consideration is to define "same body of water" to include water segments designated in State or Tribal water quality standards. This approach may result in inconsistent determinations between permitting agencies, however, particularly if there are large variations in the size of the designated individual water segments. EPA requests comment on this interpretation, including whether the final Guidance should specify a maximum limit to the size of the water segment if this element is selected in the final Guidance.

Another possible approach would be to allow permitting authorities the flexibility to interpret "same body of water" on a case-by-case basis. Factors that might be considered in this determination include whether the intake and outfall points are within the same water segment identified in State or Tribal water quality standards; whether the discharge is upstream or downstream from the intake point in flowing waters or in close proximity to the intake point in open lake waters; whether the intake pollutants would reach the outfall point within a reasonable time period in the absence of the removal and discharge back to the receiving water; or whether the water chemistry (e.g. hardness and pH) are similar. Based on consideration of these factors, for example, a permitting authority might determine that a discharge is to the same body of water where intake waters are taken from a relatively clean tributary of a relatively dirty body of water and discharged to the latter body in close proximity to where the tributary itself flows into the larger water body. EPA also requests comment on whether and, if so, under what circumstances the phrase "same body of water" should be interpreted to cover waters within the same watershed. For example, should the phrase "same body of water" encompass intake waters taken from a relatively clean water body and discharged into another water body containing the pollutant at higher concentrations where both water bodies are within the same watershed. EPA requests comment on the interpretation of "same body of water" and identification of any additional factors that the permitting authority should evaluate in making this determination. EPA also requests comment on any alternative interpretations of this phrase.

The second condition that the permittee would need to demonstrate to

be eligible for procedure 5.E of appendix F is that it does not contribute any additional mass of the specified intake water pollutant to its wastewater. Contributions include pollutants discharged to the process waste stream, corroded from the facility's pipes, or that are introduced from intake water sources other than the receiving water. The pollutant present in the discharge must be due solely to its presence in intake water from the receiving water body.

EPA believes that this provision may be necessary to implement the statutory and regulatory requirements discussed above, and to further the goals of the CWA and GLWQA to restore and maintain the physical, chemical and biological integrity of the Nation's waters. In non-attained waters, restoration can only be achieved by removal or natural degradation of past pollutant loadings or by reduction in future pollutant loadings. One reasonable step towards restoration of non-attained waters is to limit application of the proposed provisions of procedure 5.E.1.b. of appendix F to facilities that do not contribute any additional mass of a pollutant from its process waste stream.

The determination whether the discharge contributes an additional mass of the intake water pollutant should be based on monitoring data and information on the kinds of pollutants generated by the particular type of facility. For example, a facility would monitor the effluent flow (volume per day) and effluent pollutant concentration, and then would calculate the mass of the pollutant by multiplying the effluent flow by a conversion factor to transfer the volume of water into mass of water, and then multiplying by the concentration. If adequate data do not exist to make this determination, the permitting authority would apply the reasonable potential procedures in procedure 5.A through 5.D of appendix F. EPA invites comment on all aspects of this provision including the interpretation of "contribution of no additional amount," the data discussed for making this determination, the use of statistical methods to make this determination, and whether minimum data requirements should be specified in the final regulation.

The third condition the permittee would need to demonstrate to be eligible for proposed procedure 5.E of appendix F is that it does not alter the identified intake water pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur from the discharge that would not occur if the pollutant was left in-stream. Alterations may occur as long as they do not cause adverse water quality impacts. An example of the type of alteration that would cause adverse water quality impacts would be a change in pH or temperature that affects the structure of some pollutants contained in non-contact cooling water such that the toxic effects associated with the effluent pollutants are increased. Another example is where a facility reduces the hardness of its water, thereby increasing the toxicity of a metal. However, simple removal of a portion of the pollutants through treatment is not considered to be an alteration that would cause adverse water quality impacts. If the permittee does not demonstrate to the satisfaction of the permitting authority that an intake pollutant is not chemically or physically altered in a manner that would cause adverse water quality impacts, the permitting authority must determine the necessity for and level of any appropriate WQBEL for the altered pollutant according to the reasonable potential procedures in procedures 5.A through 5.D of appendix F after consideration of the individual facts.

EPA invites comment on all aspects of this provision including the interpretation of "chemical and physical alteration," the interpretation of "adverse water quality impacts", the specific environmental and pollutant parameters needing evaluation for making this determination, the use of statistical methods to make this determination, and whether minimum data requirements should be specified in the final regulation. For example, should the final rule include a list of environmental parameters such as hardness, pH, and percent of the pollutant in the dissolved state for determining if the pollutant is altered. Also, should the final rule specify the maximum extent to which these environmental parameters can change without causing an adverse impact on water quality.

The fourth condition the permittee would need to demonstrate to be eligible for proposed procedure 5.E of appendix F is that the pollutant is not concentrated at the edge of any available mixing zone after discharge from the facility. Attainment of water quality standards generally is measured by comparing the concentration of a pollutant in an ambient water to the water quality criterion which is represented as a concentration. A non-attained surface water is one where the ambient concentration exceeds the water quality criteria at the edge of a mixing zone, if one is allowed by State water quality standards, or at the end of a discharge pipe, if the water quality standards prohibit mixing zones. Facilities that further concentrate pollutants at the edge of a mixing zone, especially in non-attained waters, may contribute to an exceedance of water quality standards. Accordingly, proposed procedure 5.E of appendix F does not apply if there is an increase of the pollutant concentration at the edge of a mixing zone as compared to the pollutant concentration in the intake water; if no mixing zone is allowed by a State's water quality standards, the appropriate comparison is instead to the point of discharge. However, proposed procedure 5.E of appendix F would allow consideration of increased concentrations at the edge of any allowable mixing zone to accommodate water conservation in order to be consistent with the proposed provisions in procedure 3 of appendix F that allow the continued use of mixing zones when water conservation measures would result in increased pollutant concentrations without increases in mass loadings. EPA invites comment on all aspects of this provision including the interpretation of "no concentration"; whether a particular statistical methodology for measuring "no concentration" should be included in the final Guidance; and whether any provision in the final Guidance for intake water pollutants should allow consideration of a maximum increased concentration resulting from evaporation of cooling water.

The fifth condition that the permittee would need to demonstrate to be eligible for proposed procedure 5.E of appendix F is that the timing and location of the effluent discharge does not cause adverse water quality impacts to occur from the simple pass-through of an intake water pollutant that would not occur if the pollutant were left in-stream. This condition is designed to protect the water body from adverse impacts that could result if intake water were withdrawn, for example, at high flow conditions and discharged at low flow conditions or at high tide and discharged at low tide. EPA is aware that in some cases, differences due to timing of the discharge would not cause adverse water quality impacts, but believes that there are some cases where timing differences would cause adverse impacts that must be considered by the permitting authority.

This condition also ensures that the location of the effluent discharge does not cause adverse water quality impacts to occur from the simple pass-through of an intake water pollutant that would not otherwise occur if the pollutant were left in-stream. An example where there

may be an adverse water quality impact is where the intake pipe is located mid-stream, and the discharge is at the edge of the river bank where there is a critical habitat for a breeding population of fish. Another example is where the intake and outfall pipes are within the same body of water but several miles apart. The size of a water body segment designated by the State or Tribe may vary substantially. One large river segment, for example, may contain both portions that are in compliance with the designated use and water quality criteria, and portions that exceed criteria due to other dischargers. Under this circumstance, adverse impacts might occur if the intake pipe was located in the non-attainment portion of the water body and the discharge was to the higher quality water further upstream. Accordingly, EPA believes that the permitting authority should evaluate the possibility of adverse impacts due to the location of the intake and outfall pipes as a condition of granting relief under proposed procedure 5.E of appendix F. EPA invites comment on all aspects of this condition including whether the final regulation should specify a maximum distance between the intake and outfall or a maximum time interval between intake and discharge to be eligible for proposed procedure 5.E of appendix F.

Proposed procedure 5.E. of appendix F of part 132 identifies three conditions that the permitting authority must address in the NPDES permit or fact sheet if it determines under procedure 5.E of appendix F that simple pass-through of an identified intake water pollutant does not have the reasonable potential to cause or contribute to an exceedance of a water quality standard. First, the permitting authority must summarize the basis for the determination that there is no reasonable potential for the discharge of an identified intake water pollutant to cause or contribute to an excursion above a narrative or numeric water quality criterion within a State water quality standard in the NPDES permit fact sheet or statement of basis. This would include evaluation of the permittee's demonstration of the five specified conditions discussed above. Documentation of all calculations and rationales is required by the existing NPDES regulations at 40 CFR 124.7.

Second, proposed procedure 5.E of appendix F would require that the permit require all monitoring of the influent, effluent and ambient water necessary to determine that the conditions of procedure 5.E of appendix F are maintained during the permit term. Appropriate monitoring is necessary, for example, to identify changes in the mass or concentration of an intake water pollutant or introduction of a new source of the identified pollutant through the facility's waste stream. The selection of appropriate monitoring requirements may vary based on consideration of the individual circumstances at each facility or within the receiving water. Accordingly, EPA believes that permitting authorities should identify the appropriate monitoring parameters and frequencies to be included in the NPDES permit based on their best professional judgment. EPA invites comment on this condition, including whether the final Guidance should specify minimum monitoring requirements for all facilities, whether permitting authorities should be required to consider specified factors in making this determination, or whether other permit conditions would be adequate in lieu of the proposed monitoring provisions.

Third, proposed procedure 5.E of appendix F would require that the permit contain a reopener clause authorizing the permitting authority to modify or revoke and reissue the permit if new information demonstrates changes in any of the conditions of procedure 5.E of appendix F. For example, a facility may obtain a different source of intake water or may relocate its discharge into a different receiving water. In these instances, new amounts of pollutants are added to the receiving water for the first time. Similarly, monitoring may demonstrate that an intake water pollutant is altered by some change in the process waste stream subsequent to permit issuance. In either circumstance, the permitting authority must evaluate whether a WQBEL is necessary given the changed circumstance. This condition is consistent with EPA's authority to modify permits for new information under 40 CFR 122.62(a)(2).

The last part of the proposed language for proposed procedure 5.E of appendix F addresses the relationship between the option and any available waste load allocation (WLA) or total maximum daily load (TMDL). The proposed provisions of procedure 5.E of appendix F do not alter the permitting authority's existing obligation to develop effluent limits consistent with the assumptions and requirements of any WLA or TMDL that is developed by the State and approved by EPA. (40 CFR 122.44(d)(1)(vii).)

Similarly, application of procedure 5.E of appendix F, if finalized, would not alter a State's obligation to identify water quality-limited segments and establish priorities for conducting TMDLs for those waters under 40 CFR 130.7. The required evaluation of existing and available water quality data to make these determinations under existing § 130.7(b)(5) would include consideration of the information submitted or generated to support permit decisions under procedure 5.E of appendix F.

If the permitting authority cannot make the determination under procedure 5.E of appendix F for any reason, then the permitting authority would need to use the procedures under procedure 5.A through 5.D of appendix F for determining whether a discharge has the reasonable potential to cause or contribute to an exceedance of water quality standards. Additionally, ineligibility of a facility for the simple pass-through determination of procedure 5.E of appendix F would not affect that facility's ability to request the application of existing mechanisms for consideration of intake water pollutants in setting WQBELs (e.g., TMDL, variance from water quality standards, and modifications to designated uses and criteria), described earlier in this preamble and in other parts of this Guidance.

Finally, § 132.4(g) of today's proposed Guidance provides that the Great Lake States and Tribes may, but are not required to, apply any of the proposed implementation procedures to the pollutants and pollutant parameters listed in Table 5 of the proposed rule at 40 CFR part 132. EPA believes that application of proposed procedure 5.E of appendix F to the pollutants in Table 5, including generic pollutant parameters (e.g., biochemical oxygen demand (BOD) and total suspended solids (TSS)), is technically feasible as long as the proposed requirements of procedure 5.E of appendix F are demonstrated. EPA invites comment on the application of the procedures to all pollutants, including identification of pollutant characteristics that may prevent demonstration of any of the proposed requirements of procedure 5.E of appendix F.

iv. *Alternative Options Considered.* EPA considered several options described below that reflect consideration of intake water pollutants in establishing water quality-based limits in addition to the proposed approach. EPA requests comment on all aspects of these alternative options.

(A) *Option 1.* Option 1 is the current National approach. EPA's existing regulations do not provide a specific mechanism to allow special credit or consideration for pollutants present in a facility's intake water when setting

WQBELs comparable to the intake credit provision for technology-based limitations at 40 CFR 122.45(g). If the permitting authority determines that a facility's discharge has the reasonable potential to cause or contribute to an exceedance of water quality standards for any pollutant in the effluent, the NPDES permit must include an appropriate WQBEL for that pollutant. EPA's existing regulations and guidance provide several mechanisms, however, that may be used to derive any WQBEL necessary to control discharges of pollutants to receiving waters that exceed water quality standards, including discharges containing those pollutants found in a discharger's intake water. These mechanisms include TMDLs, temporary variances from water quality standards, and changes in the designated use of the water body or site-specific criteria modifications. Each of these mechanisms is described above.

Option 1 is the current EPA approach. This approach forwards the CWA section 101(a) goal of restoring the physical, chemical and biological integrity of the Nation's waters. It is also consistent with requirements in CWA section 301(b)(1)(C) to include all limitations necessary in NPDES permits to meet applicable State water quality standards. Option 1 also creates an incentive for regulatory authorities to develop TMDLs for non-attainment waters consistent with the requirements of CWA section 303(d). CWA section 303(d) is designed to remedy existing in-stream excursions above State water quality standards and can be used to fairly allocate the burden of reducing undesirable discharges among all sources, point and nonpoint. Finally, Option 1 also allows use of temporary variances in the Great Lakes System to the extent provided under National regulations and site-specific criteria modifications to the extent described in section VIII.A above.

Some States have expressed concern with the use of these existing mechanisms to address discharges of intake water pollutants to non-attainment waters. For example, approval of a variance or site-specific modification to a water quality criterion requires time for public participation and extends the duration of the permit issuance process. In addition, completion and approval of a TMDL may require additional time for evaluation of available data and could also extend the duration of the permit issuance process. Delays in permit issuance may impose additional costs on facilities and permitting authorities. Based on these concerns, the Initiative Committees believed that the proposed Great Lakes Guidance should present additional mechanisms to address intake water pollutants.

If EPA selects Option 1 in the final Guidance, no regulatory language would be included to specifically address intake water pollutants. EPA believes that the existing mechanisms in Option 1 generally provide sufficient procedures to address discharges to non-attainment waters, including discharges that contain intake water pollutants. As discussed above, however, EPA is also soliciting comment on the adoption of proposed procedure 5.E of appendix F to specifically address the simple pass-through of unaltered intake water pollutants in addition to continued application of these existing mechanisms.

(B) *Option 2.* EPA is also considering whether to include a provision in the final rule that would allow the permitting authority to directly modify WQBELs to reflect a credit for intake water pollutants if the pollutants are discharged to the same body of water as the intake water. A specified level of credit would be allowed under this approach even when the facility contributes an additional amount of the intake water pollutant from its process waste stream. However, credit would be precluded under Option 2 if the facility failed to demonstrate the remaining conditions specified in section 5.E.1.a, c, d, and e of proposed procedure 5.E of appendix F. For example, credit would be precluded under Option 2 similar to the proposed procedure 5.E of appendix F if the facility altered the identified intake water pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not have occurred if the pollutant was left in-stream; concentrated the intake water pollutant at the edge of the mixing zone (or end of pipe if a mixing zone is prohibited) as compared to the concentration in the intake; withdrew intake water from a different body of water than the receiving water; or discharged at a time or location that may cause adverse effects to occur that would not occur if the pollutant was left instream.

Option 2a would allow a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant withdrawn from the receiving water. If a facility is able to remove any of the pollutant from the intake water either before use at the facility or during wastewater treatment, the facility could offset this reduction by increasing the amount of the pollutant contributed by the process wastewater.

Option 2b would allow a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant in the intake water after deduction of the amount removed by the facility's treatment system prior to use of the intake water in the facility. This variation could result in a lower discharge than allowed under option 2a. If a facility removes any of the pollutant originating in the intake water prior to use at the facility, the facility would not be able to offset this reduction. If a facility is able to remove any of the intake water pollutant during the treatment process, however, it would be able to increase the amount of the pollutant contributed in the process wastewater. The following scenario demonstrates application of options 2a and 2b.

A facility is located on a river segment with a lead concentration of 50 µg/L that exceeds the State water quality criteria of three µg/L. The facility withdraws 200,000,000 liters/day (53 million gallons/day) of water at a concentration of 50 µg/L; this corresponds to 10 kg/day of lead in the intake water. The facility treats its intake water prior to use in the industrial process to remove solids; this treatment removes 60 percent of the lead (six kg/day). The facility's wastewater treatment system removes 90 percent of lead from the combination of the intake water and process waste water and discharges the remaining 10 percent.

Option 2a would allow the facility to discharge an effluent containing the same mass of lead withdrawn from the receiving water, i.e., 10 kg/day of lead. Under this scenario, the facility could contribute 96 kg/day of lead from its process waste stream prior to treatment and still be able to discharge the same mass of lead withdrawn from the river, that is, 10 kg/day. This calculation is expressed as (10 kg − 6 kg + 96 kg)(0.10) = 10 kg.

Option 2b would allow the facility to discharge an effluent containing the same mass of lead withdrawn from the receiving water after deduction of the amount removed by the facility prior to use in the process stream, i.e., four kg/day of lead. Under this scenario, the facility could contribute 36 kg/day of lead from its process waste stream prior to treatment. The facility would, however, have the net environmental benefit of removing six kg/day of lead from the river even though it is discharging pollutants that did not originate from the receiving water. This calculation is expressed as (10 kg − 6 kg + 36 kg)(0.10) = 4 kg. The amount of discharge allowed under Option 2b would be greater for a facility that did

not have to pretreat its intake water to fulfill industrial process needs.

In developing NPDES permit conditions under Option 2, a permitting authority would need to require sufficient information and monitoring of the intake water quality to determine the appropriate WQBEL, including information on the restrictions identified as part of the proposed procedure 5.E of appendix F (e.g., alteration of the pollutant, concentration at the edge of the mixing zone, and time and location of the discharge). In addition, the permitting authority would need to require intake water monitoring during the permit term to determine if ambient concentrations decrease, and include a specific reopener provision in the permit to allow the permit modification to address any changed circumstances including changed concentrations in the intake water similar to the proposed requirements of the proposed procedure 5.E of appendix F.

Finally, neither option 2a or 2b would alter the authority of the regulatory or permitting authority to develop WQBELs to account for the presence of intake water pollutants pursuant to a TMDL, temporary variance, or other allowable modifications to water quality standards pursuant to State and EPA regulations and this proposed Guidance. If a TMDL was developed, effluent limitations derived using Option 2 would need to be adjusted so that the TMDL was not exceeded.

Similarly, if EPA finalized a direct mechanism to modify WQBELs to reflect a credit for discharges containing intake water pollutants, application of this mechanism would not alter a State's obligation to identify water quality-limited segments and establish priorities for conducting TMDLs for those waters under 40 CFR 130.7. The required evaluation of existing and available water quality data to make these determinations under existing § 130.7(b)(5) would include consideration of the information submitted or generated to support these permit decisions.

There are some advantages to this option. In particular, this approach would explicitly recognize that the receiving water is the original source of some or even all of the pollutants discharged by the facility and provide a direct mechanism for adjusting the NPDES effluent limitations to reflect this contribution from the intake water. Option 2 does not require a facility to remove constituents from the intake water prior to discharging the water back to the receiving water. The mechanism provided by Option 2 would not delay permit issuance; in contrast, the mechanisms available under EPA's current regulations may delay permit issuance as discussed in Option 1 above. This approach would at least assure that current water column concentrations that exceed either Tier I criteria or Tier II values would not be increased.

Further, EPA recognizes that in some instances, Option 2 could result in reductions in water column concentrations which may improve the overall water quality. These instances could occur where a facility discharges less than the mass of a pollutant that it removed from its intake water. For example, if a facility's intake water contained 10 kg/day of lead, the current treatment system removed 6 kg/day of the intake pollutant, and the facility offset 3 kg/day of the removed amount with waste stream pollutants (i.e., the facility discharged 7 kg/day of lead), the water quality may improve because of the overall decrease in the mass of lead in the water. Whether this discharge would result in water quality improvements, however, would depend on several factors including the magnitude of the actual decrease in the pollutant concentration in the water column, the lowered concentration in the water column as compared to the water quality criterion, and consideration of the factors identified in the proposed procedure 5.E of appendix F (e.g., alteration of the pollutant, concentration at the edge of any applicable mixing zone, and time and location of the discharge).

EPA has several concerns, however, about Options 2a and 2b. First, both options 2a and 2b may be viewed as inconsistent with the CWA and GLWQA goals of restoring the physical, chemical and biological integrity of the Nation's waters. In non-attained waters, restoration can only be achieved by removal or natural degradation of past pollutant loadings or by reduction in future pollutant loadings. Option 2a does not produce any further reduction in pollutant levels because the facility may discharge waste stream pollutants up to the total pollutant mass in the intake water. Option 2b provides some reduction because any pollutant mass removed by a facility prior to use of the intake water in the process system cannot be returned to the surface water. However, option 2b also allows any further removal of pollutants by the facility's wastewater treatment system to be replaced by an increased discharge of the pollutants from the process waste stream. Therefore, both options allow offset of incidental removal of pollutants in whole or in part by contributions from facility discharges.

Second, Option 2 may be interpreted as inconsistent with EPA's existing regulation of intake water pollutants for technology-based limitations. The NPDES regulation at 40 CFR 122.45(g)(3) provides that the credit shall be granted "only to the extent necessary to meet the applicable limitation or standard up to the influent value." This regulation does not provide full credit in the calculation of technology-based limitations for all pollutants contained in intake water, but instead precludes credit for pollutants removed by the existing or proposed intake and effluent treatment systems.

In the preamble to the final rulemaking promulgating 40 CFR 122.45(g)(3), EPA discussed a comment that asserted that a simple subtraction of intake pollutant values from effluent values should be made when setting technology-based permit limits and measuring compliance. EPA rejected this argument in part because:

> To grant a net/gross credit may give an unfair advantage to facilities with measurable levels of pollutants in their intake waters. Such facilities, by relying on intake credits, could "comply" with effluent limitations by utilizing a lower level of treatment than their competitors on cleaner streams * * *. Furthermore, intake pollutants rarely pass through a facility and all its associated intake and/or effluent treatment without some removal and/or complicated exchange of pollutants * * *. [T]he current regulation * * * does not allow a full credit, but only a credit after consideration of removal in intake and effluent treatment systems. Today's regulation replaces that complicated calculation with a more simple approach of granting credit as needed to meet technology-based standards. (49 FR 38026 (September 26, 1984)).

Option 2 could be viewed as inconsistent with this position by allowing facilities to replace pollutants removed by treatment of the effluent (and, under option 2a, treatment of the influent as well) with additional pollutants from their process waste stream prior to discharge.

Additionally, although adjustment of technology-based limits is appropriate to reflect intake water pollutants under narrow circumstances, EPA believes that a similar direct credit provision to adjust WQBELS may not be appropriate because of the fundamental differences between the two types of permit limitations. The authority for establishing the existing intake regulation is derived from EPA's authority to establish technology-based effluent limitations under sections 301, 304, and 306 of the CWA. Under those

sections, EPA must develop increasingly stringent effluent limitations based on the improving technological capabilities of treatment plants. In developing this mechanism to adjust technology-based effluent limitations, EPA recognized that the presence of pollutants in intake water may in some circumstances prevent a facility from obtaining the statutorily mandated level of pollutant removal (e.g., BPT, BAT, or BCT). Under those circumstances, the failure to allow adjustment of technology-based limitations to reflect the pollutants would in effect impose a higher level of control than statutorily required. The authority to establish WQBELs, in contrast, is derived primarily from section 301(b)(1)(C). This section requires application of "any more stringent limitation * * * necessary to meet water quality standards" after application of technology-based controls.

Third, EPA is concerned that both options 2a and 2b would allow facilities to discharge pollutants originating from a process waste stream into a surface receiving water that currently exceeds an applicable water quality criterion. In the absence of a temporary variance from existing water quality standards, site-specific modifications to criteria or designated uses, or an appropriate wasteload allocation pursuant to a TMDL, EPA believes that the permitting authority should establish appropriate WQBELs to control discharge from process wastewaters if they have the reasonable potential to cause or contribute to an exceedance of existing State water quality standards.

Fourth, Option 2 may create an economic incentive for facilities to relocate to water bodies that are the most polluted, that is, have the highest ambient pollutant concentrations. Under both options 2a and 2b, the amount of a pollutant that a facility could discharge is not based solely on attainment of water quality standards; in these cases, the amount of the pollutant currently in the receiving water and the efficiency of the facility's treatment systems also affect the effluent limitations. Wastewater treatment systems generally are able to remove a set percentage of a pollutant mass in the influent to the wastewater treatment system. (There are exceptions to this general concept but these occur when the influent concentrations are greatly dissimilar, e.g., one influent concentration is near the analytical method detection limit and the other is greater by a factor of 10 or more.) As a result, the higher the ambient pollutant concentration, the greater the pollutant mass that a facility could discharge.

In the previous example used to describe Option 2a, the facility removed 10 kg/day of lead from the river and was able to contribute 96 kg/day from its process wastewater in order to achieve a discharge requirement of 10 kg/day. If the concentration in the river at the intake was double (100 µg/1), Option 2a would allow the facility to discharge more of the pollutant (20 kg/day of lead). Under this condition of a higher concentration in the intake water, the facility could contribute 192 kg/day of lead from its process waste stream prior to treatment. This calculation is expressed as (20 kg − 12 kg+192 kg)(0.10)=20 kg. Therefore, the higher the pollutant concentration in the receiving water, the more of that pollutant that the facility can contribute from its process wastewater under Option 2a before it is treated and still discharge the same mass of lead withdrawn from the river.

The same principle holds for Option 2b. Under the example used to describe Option 2b, the facility is able to discharge 4 kg/day of lead which represents the mass removed from the river by the intake after discounting the amount removed by the facility prior to use in the process. The facility was able to contribute 36 kg/day from its process wastewater in order to achieve a discharge requirement of 4 kg/day. If the concentration in the river at the intake was double (100 µg/L), Option 2b would allow the facility to discharge more of the pollutant (8 kg/day of lead). Under this condition of a higher concentration in the intake water, the facility could contribute 72 kg/day of lead from its process waste stream prior to treatment. This calculation is expressed as (20 kg − 12 kg + 72 kg)(0.10) = 8 kg. Therefore, the higher the pollutant concentration in the receiving water, the more of that pollutant that the facility can contribute from its process wastewater under Option 2b before it is treated and still discharge the same mass of lead withdrawn from the river less the amount removed by the facility prior to use in the process.

EPA is concerned that any incentive for facilities to relocate to surface waters that are more polluted may be interpreted as inconsistent with the shared goal of the CWA and the GLWQA to restore the physical, chemical and biological integrity of the Nation's waters. In non-attained surface waters, restoration can only be achieved by removal or natural degradation of past pollutant loadings or reduction in future pollutant loadings. Creating an incentive for facilities to relocate to non-attained waters may delay or frustrate achievement of this goal.

EPA requests comment on all aspects of Option 2, including whether any consideration of this approach should be limited to intake water pollutant discharges that result in a minimum specified decrease in the total mass of the pollutant in the receiving water and/or improvement in water quality. EPA also requests comment on the conditions that would be necessary to demonstrate improvement in water quality under these circumstances; any appropriate methods for determining decreases in total pollutant mass; and whether a specified minimum level of decrease should be required for this option. For example, should this approach, if adopted, specify a minimum percent reduction in the ambient concentration of the pollutant or require that the ambient concentration after discharge be within a certain percentage of the water quality criterion.

Finally, EPA requests comment on whether application of a mechanism to modify WQBELs to directly reflect credit for intake water pollutants, if adopted, should be limited to one permit term (a maximum of five years) absent State completion of a TMDL for the water quality-impaired receiving water. As discussed further above, existing § 130.7 currently requires States to identify water quality-limited segments and establish priorities for conducting TMDLs for those waters. A time limitation on the availability of intake credits under Option 2 may facilitate restoration of water quality-limited segments by encouraging timely development of appropriate wasteload allocations and load allocations for all discharges into these impaired waters. EPA requests comment on this limitation, including the reasonableness of a restriction to one permit term, and on all other aspects of Option 2.

(C) *Option 3.* EPA considered another option that would allow the permitting authority to directly modify WQBELs to reflect a credit for intake water pollutants regardless of where the intake water source is located. Option 3 is similar to Option 2 in all aspects except that Option 3 extends the concept of intake credits for WQBELS to situations where all or a portion of the intake water source is a different body of water than the receiving water. EPA considered three variations to this option.

Option 3a would allow a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant that the facility receives from any water source including sources other than the receiving water. If a facility is able to remove any of the

pollutant from the intake water, the facility could offset this reduction by increasing the amount of the pollutant contributed by the process wastewater.

Option 3b would similarly allow a facility to discharge an effluent containing, at a maximum, the same mass of the pollutant contained in intake water from any source after deduction of the amount removed by the facility's treatment system prior to use of the intake water in the facility. If a facility is able to remove any of the pollutant originating in any intake water through wastewater treatment, the facility could similarly offset this reduction by increasing the amount of the pollutant contributed by the process wastewater.

Option 3c would allow a facility to discharge an effluent containing, at a maximum, the same concentration of the pollutant that is present in the receiving water. If a facility is able to remove any of the pollutant from the intake water, the facility will be able to offset this reduction by increasing the amount of the pollutant contributed by the process wastewater. The following scenario demonstrates application of options 3a, 3b, and 3c.

A facility is located on a river segment with a lead concentration of 50 µg/L that exceeds the State water quality criteria of three µg/L. The facility obtains 200,000,000 liters/day (53 million gallons/day) of water at a concentration of 10 µg/L from a nearby lake; this corresponds to two kg/day of lead in the intake water. The facility treats its intake water prior to use in the industrial process to remove solids; this treatment removes 60% of the lead (1.2 kg/day). The facility's wastewater treatment system removes 90 percent of lead from the combination of the intake water and process wastewater and thereby discharges the remaining 10 percent.

Option 3a would allow the facility to discharge an effluent to the river which contains the same mass of lead in the water removed from the lake, i.e., two kg/day of lead from the lake. Under this scenario, the facility could contribute 19.2 kg/day of lead from its process waste stream prior to treatment. This calculation is expressed as (2 kg − 1.2 kg+19.2 kg)(0.10)=2 kg. This discharge also would increase the lead mass in the river by two kg/day.

Option 3b would allow the facility to discharge an effluent to the river which contains the same mass of lead withdrawn from the lake after deduction of the amount removed by the facility prior to use in the process stream, i.e., 0.8 kg/day of lead. Under this scenario, the facility could therefore contribute 7.2 kg/day of lead from its process waste stream prior to treatment. This calculation is expressed as (2 kg − 1.2 kg+7.2 kg)(0.10)=0.8 kg. This also would increase the mass in the river by 0.8 kg/day.

Option 3c would allow the facility to discharge an effluent to the river which contains the same concentration of lead as in the receiving water. In the example, the river has a concentration of 50 µg/l. The facility would be able to discharge 10 kg/day of lead to the river which represents a discharge of 200,000,000 l/day at a concentration of 50 µg/l. Under this scenario, the facility could contribute 99.2 kg/day of lead from its process waste stream prior to treatment. This calculation is expressed as (2 kg − 1.2 kg+99.2 kg)(0.10)=10 kg. This discharge also would increase the lead mass in the river by 10 kg/day.

In developing NPDES permit conditions under Option 3, as with Option 2, a permitting authority would need to require sufficient monitoring of the intake water quality to determine eligibility for and compliance with appropriate WQBELs and incorporate a specific reopener provision in the permit to allow permit modification to address any changes in the ambient concentration of the pollutant. Also consistent with Option 2, Options 3a, 3b, and 3c would not alter the authority of the regulatory or permitting authority to develop WQBELs to account for the presence of intake water pollutants pursuant to a TMDL, temporary variance, or other allowable modifications to water quality standards pursuant to State and EPA regulations and this proposed Guidance. If a TMDL was developed, effluent limitations derived using Option 3a, 3b, or 3c would need to be adjusted so that the TMDL was not exceeded.

Option 3 has the same advantages as identified above for Option 2. In particular, the option would recognize that the intake water is the original source of some or all of the pollutants discharged by the facility and provides a direct mechanism for adjusting the facility permit limits to reflect this contribution. For example, where a facility receives its intake water from a commercial or public water supplier, this approach allows the facility to discharge into the receiving water the same amount of pollutants, either treated or untreated, as present in the intake water.

EPA recognizes that in some instances Option 3 could result in reductions in water column concentrations which may improve the overall water quality. These instances could occur if a facility discharges less than the concentration of a pollutant that is present in the receiving water. For example, if a facility discharged an effluent containing 10 µg/l of lead into a river with a concentration of 50 µg/l, the discharge may dilute the ambient concentration and therefore lower the river concentration. Although the ambient concentration could be lower, however, the mass of a pollutant would increase by the transfer of pollutants to a different body of water. Whether this discharge would result in overall water quality improvements would depend on several factors including, the magnitude of the actual decrease in the pollutant concentration in the water column, the lowered concentration in the water column as compared to the water quality criterion, consideration of the factors identified under the proposed procedure 5.E of appendix F (e.g., alteration of the pollutant, concentration at the edge of any applicable mixing zone, and time and location of the discharge), the impacts of additional mass on pollutant levels in sediment and fish tissue, and the transfer of the additional mass through volatilization and sedimentation into nonpoint sources of atmospheric deposition and sediment resuspension. In particular, the additional mass of a persistent pollutant may offset some of the environmental benefits of lowering water concentrations because the additional mass, if cycled through sediments by deposition and resuspension, could delay the date of achieving the water quality criterion.

EPA has several concerns, however, with options 3a, 3b or 3c of the proposed Guidance. In addition to the reasons discussed for options 2a and 2b, options 3a, 3b and 3c would allow facilities to increase the mass of pollutants in a surface receiving water that currently exceeds an applicable water quality criterion. Under Option 3, the pollutants in the intake water originated from outside the water body and would otherwise not be introduced into the receiving water except for the discharge of the facility. The approach of Option 3 therefore may be interpreted as inconsistent with the CWA and GLWQA goals of restoring the physical, chemical and biological integrity of the Nation's waters. In non-attained waters, restoration can only be achieved by removal or natural degradation of past pollutant loadings or by reduction in future pollutant loadings. Options 3a, 3b and 3c increase the pollutant levels by increasing the pollutant mass in the receiving water.

Option 3 is also inconsistent with the structure and function of State water quality standards under the CWA. Water

quality standards include State designated uses and criteria to ensure protection of those uses for a specified water body or water segment. Option 3 would allow facilities to introduce pollutants from a different body of water for the first time without determining whether the new discharge has the reasonable potential to cause or contribute to an exceedance of applicable water quality criteria for the receiving water.

EPA requests comment on all aspects of Option 3, including whether any consideration of this approach should be limited to intake water pollutant discharges that result in a specified minimum decrease in the concentration of the pollutant in the receiving water and/or improvement in water quality. EPA also requests comment on the conditions that would be necessary to demonstrate improvement in water quality under these circumstances; any appropriate methods for restricting increases in total pollutant mass; and whether a specified maximum level of mass increase should be required for this option. EPA also requests comment on whether this option should only be considered for those pollutants that do not bioconcentrate in aquatic organism tissue or accumulate in sediments. For example, should this approach if adopted specify a minimum percent reduction in the ambient concentration of the pollutant or require that the ambient concentration after discharge be within a certain percentage of the water quality criterion or require a maximum allowable increase in the mass loading to the water.

(D) *Option 4.* This option is the initial procedure developed by the Great Lakes Technical Work Group during the Initiative process. Option 4 is presented below in its entirety from the December 6, 1991 version. This version was originally included in the Great Lakes Implementation Guidance as Part 11.B (now procedure 3 of appendix F to part 132) and is listed below:

B. *Background concentrations greater than the water quality standard or criteria.* This section includes provisions for determining effluent limitations when the background concentration of a pollutant in a receiving water exceeds an applicable water quality standard or criterion. In applying these provisions, however, all effluent limitations derived by this provision must not cause any applicable TMDL to be exceeded. In such cases, the effluent limitations shall be adjusted so that the TMDL is not exceeded.

(1) *Point sources using water from a source other than the water body to which the effluent is discharged.*

(a) Whenever the representative background concentration for a toxic substance in the receiving water is determined to be greater than any applicable water quality standard or criterion for that substance and the source of at least 90 percent of the wastewater is from groundwater or a public drinking water supply system, the concentration value of the WLA for that substance, shall be equal to the lowest applicable water quality standard or criterion except as provided by part B.(1)(b). POTWs which discharge to the same surface water from which the water supply is withdrawn shall be subject to part B(2). of this procedure.

(b) The concentration value of the WLA may be established at a concentration greater than the water quality standard or criterion for the substance in the receiving water as required by part B.(1)(a) in a range up to, but not greater than the representative concentration of the substance in the receiving water. The WLA shall only be increased above the standard or criterion if it is demonstrated to the permitting agency that the concentration of the substance in the groundwater or public drinking water supply system at the point of intake exceeds that applicable standard or criterion for that substance and that reasonable, practical or otherwise required methods are implemented to minimize the addition of the toxic substance to the wastewater. This part shall not apply where groundwater is withdrawn from a location of contaminated groundwater.

(2) *Point sources using water from the same water body to which the effluent is discharged.*

(a) Whenever the representative background concentration of a toxic substance in the receiving water is determined to be greater than any applicable water quality standard or criterion for that substance and the source of more than 10 percent of the wastewater for any discharger is from the same receiving water, the concentration value of the WLA for that substance shall equal the representative background of that substance in the receiving water. In addition, or as an alternative, the mass value of the WLA may be established at a value which requires that there be no net addition of the toxic substance in the wastewater as compared to the intake or source water.

Option 4 represents a combination of Options 2a and 3c. The procedure provides mechanisms for reflecting a credit for pollutants in a facility's intake water under two circumstances.

First, when at least 90 percent of the intake water source is from ground water or public drinking water supply, Option 4 would allow a facility to discharge an effluent containing a concentration of a pollutant ranging from, at the low end, the water quality criterion, to, at the high end, the concentration of the pollutant in the receiving water. The permitting authority would use its professional judgment and would consider the reasonable, practical, and required methods to minimize addition of toxics in deciding where to establish the effluent limitation within the range of possible effluent limitations.

Second, when a minimum of 10 percent of wastewater is from the same water body into which the effluent is discharged, Option 4 would allow a facility to discharge an effluent at a concentration equal to the receiving water or containing a mass of a pollutant equal to the mass the facility receives from the water body. This option would apply even if 90 percent of the wastewater is from the process waste stream or from waters other than the receiving stream.

The same scenarios used to illustrate options 2a and 3c and permitting considerations can also be used to illustrate application of this option. EPA has concerns about Option 4 in the proposed Guidance similar to those expressed above for options 2a and 3c In addition, the requirement that effluent limitations must be consistent with the provisions of a TMDL is not sufficient to resolve the deficiencies of this option. There is no guarantee that a TMDL will be developed for any particular water body that accounts for all significant point and nonpoint sources and the option alone does not ensure attainment of water quality standards in the receiving waters.

EPA is also concerned that Option 4 would not prevent facilities from discharging pollutants that, although equal in mass to that in the intake water, may be biologically more active and thereby cause a greater adverse impact on the receiving water than leaving the pollutants in place. As previously discussed, EPA recognizes that impairment of water quality is determined by both the magnitude of a pollutant and its chemical affects on the environment. This led to the proposal of the provisions of proposed procedure 5.E of appendix F that a facility not contribute additional mass of the pollutant, or alter an intake water pollutant chemically or physically, or discharge at a time or location that may cause adverse impacts to occur which would not occur absent removal and redischarge of the pollutants.

Finally, EPA recognizes that in some instances Option 4 could result in reductions in water column concentrations which may improve the overall water quality in circumstances and for reasons identical to those discussed previously for Option 3. EPA requests comment on all aspects of Option 4, including the issues identified for comment under Options 2 and 3.

v. *Request for Public Comment.* EPA invites public comment on all aspects of the proposed Guidance and all other options for procedure 5.E of appendix F

for determining whether a discharge has the reasonable potential to cause or contribute to an excursion of water quality standards, including the specific issues and alternatives for public comment identified throughout this preamble. Additionally, EPA requests public comment on any additional options for consideration, including new options based on consideration or combination of factors discussed in the preamble.

EPA intends to include a provision in the final Guidance specifying the extent to which permitting authorities in the Great Lakes may consider the presence of intake water pollutants when establishing water quality based effluent limitations. EPA requests comment on all aspects of this subject, including all issues raised in the preamble discussion above, and any suggested alternative requirements or combinations of requirements to address the subject and issues in the final rule.

In addition, EPA invites comment on whether any finalized requirements addressing intake water pollutants should be restricted only to those pollutants that, due to nonpoint source contributions such as atmospheric deposition, are present throughout the Great Lakes Basin at about the same concentration which already exceeds the water quality criterion. The presence of these pollutants was a primary impetus for the Steering Committee's initial development of draft provisions addressing intake water pollutants. Reductions in ambient concentrations of some of these pollutants may be very difficult to currently achieve. For example, the current ambient concentrations of PCBs may reflect more the contributions of nonpoint loadings from atmospheric deposition and contaminated sediments than from point sources. Removal of all sediments containing PCBs from the Basin may not be practical due to the amount of sediments and the availability of disposal or treatment of the sediments. Likewise, control of all contributions of PCBs into the air may not be immediately possible, particularly if the introduction of PCBs into the air occurs outside the United States. Pollutants of this type, due to their wide-spread presence in the Basin, may represent the greatest application of the options for addressing intake water pollutants.

f. *Other Applicable Conditions.* Procedure 5.F.1 of appendix F of the proposed Guidance states that effluent limitations are required to comply with other State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies. Section 301(b) of the Clean Water Act requires NPDES permits to contain effluent limitations to meet both the technology and water quality-based requirements of the CWA. The proposed Guidance addresses implementation procedures for establishing appropriate water quality-based controls and does not provide specific direction to permit authorities regarding implementation of State, Tribal or Federal technology-based requirements. In addition, State or Tribal law or regulations may require NPDES permits to include WQBELs even if the reasonable potential determination procedures in procedures 5.B.1, 5.B.2, and 5.C of appendix F would not require a WQBEL to be included in the permit. In these cases, the more stringent State or Tribal requirements may be applied pursuant to section 510 of the Clean Water Act.

Additionally, implementation of the antidegradation requirements of appendix E of the proposed Guidance may require establishment of numeric effluent limitations in a permit in order to assure that further degradation of a water body by the point source will not occur. These limitations would be set, not to ensure that a facility will achieve a numeric water quality criterion, but rather to limit increases in a facility's effluent discharge under specified circumstances consistent with the antidegradation policy.

Also, procedure 5.F.2 of appendix F provides that when the permitting authority is determining the necessity for WQBELs, information from chemical-specific, whole effluent toxicity and biological assessments must be considered independently. EPA has established a "Policy on the Use of Biological Assessments and Criteria in the Water Quality Program" (June 1991), which is available in the administrative record for this rulemaking. The policy recommends that permitting authorities fully integrate chemical specific, whole effluent toxicity and bioassessment approaches into their water quality-based toxic control programs. This policy is also discussed in the TSD at p. 22. Because each water quality assessment method has unique as well as overlapping attributes, sensitivities, and program applications, EPA believes that no single approach for detecting impacts should be considered uniformly superior to any other approach. For example, the inability to detect receiving water impacts using a biosurvey alone is insufficient evidence to waive or relax an effluent limitation established using either of the other methods. The most protective results from each assessment conducted should be used in the effluent characterization process. Similarly, the results of one assessment technique should not be used to contradict or overrule the results of the other(s).

Proposed procedure 5.F.2 of appendix F is consistent with the National policy of independent applicability. EPA invites comment on all aspects of this provision including whether the policy of independent applicability should apply to determinations of appropriate effluent limitations based on either Tier I criteria or Tier II values in the Great Lakes System.

Finally, procedure 5.F.3 of appendix F requires that permitting authorities also establish a WQBEL if the discharger has a pollutant in its effluent at detectable levels and fish tissue from the water body also contains the pollutant at levels that exceed the tissue basis of the water quality criteria. This provision applies to instances where proposed procedures 5.B and 5.C of appendix F do not project the reasonable potential of a discharger to cause or contribute to an excursion above a Tier I criterion or Tier II value but tissue data from ambient fish sampling demonstrates an excursion. These instances occur when ambient water concentration monitoring either does not include the pollutant of concern or else the pollutant is present in ambient waters at a level below the ability of analytical chemical methods to detect or quantify. Nevertheless, the presence of the pollutant in fish tissue at levels that exceed the tissue basis of the Tier I criterion or Tier II value demonstrates that the criterion or value is not met. Under NPDES regulations at 40 CFR 122.44(d)(1)(i), a WQBEL is required for that pollutant or pollutant parameter whenever there is information that demonstrates that the discharge of a pollutant causes or contributes to such an excursion. The provisions of proposed procedure 5.F.3 of appendix F implements the requirements of 40 CFR 122.44(d)(1)(i) with respect to ambient fish tissue data.

In using fish tissue data, care should be exercised by the permitting authority in determining what fish tissue data are representative of ambient conditions. For example, a fish must be expected to have lived within the geographic area of concern sufficiently long enough to have reached or approached steady state conditions in terms of bioaccumulation. Steady state occurs when the level of pollutant uptake is approximately equal to the level of pollutant elimination from the fish. EPA guidance on these considerations is provided in "Assessing Human Health Risks from Chemically Contaminated Fish and Shellfish: A Guidance Manual" (USEPA September 1989, EPA–503/8–89–002),

which is available in the administrative record for this rulemaking.

The proposed procedure 5.F.3 of appendix F compares the geometric mean of tissue samples collected from ambient fish to the tissue basis of the Tier I criterion and Tier II values for human health and wildlife protection. The tissue basis is equal to the bioaccumulation factor that was used to calculate the Tier I criterion or Tier II value multiplied by the Tier I criterion or Tier II value. The tissue basis for the same pollutant may differ for human health and wildlife criteria and values; if any tissue basis is exceeded, reasonable potential exists with respect to facilities discharging detectable levels of the pollutant.

The mean of the ambient data is used in the comparison to be consistent with the assumptions of the criteria, that is, wildlife and human consumers of fish eat an assemblage of fish. A mean best reflects this assemblage. The geometric mean is used as the most representative way to reflect the average of environmental samples. EPA invites specific comment on what characteristic of ambient data (mean, average, maximum, etc.) should be used for comparison to the tissue basis of Tier I criteria or Tier II values. EPA also invites comment on what type of mean, geometric, arithmetic, harmonic, or others, should be used for this comparison.

The proposed procedure 5.F.3 of appendix F also recognizes that there may be differences in tissue concentrations between fish samples collected from a specific water body. The reasons for this include differences in lipid content between fish, the ages of fish, and the actual exposure of individual fish. The use of a geometric mean in the comparison serves to overcome some of the inherent variability because the mean reduces the effect of any one sample. However, there may still be some variability associated with using fish tissue data. Therefore, the proposed procedure 5.F.3 of appendix F directs the permitting authority to consider the variability of a pollutant's bioconcentration and bioaccumulation in fish. The assessment of the variability may be accomplished by applying specific factors to adjust for differences in lipid content or age, or by applying an overall factor based on review of the variability in literature or field data. Whatever method is used by the permitting authority must be described in the administrative record supporting the permit decision. EPA invites comment on whether the final Guidance should allow permitting authorities to determine this variability on a site-specific basis, or otherwise include specific procedures for addressing each part of the variability or a uniform factor to address overall variability.

The proposed procedure 5.F.3 of appendix F applies to all facilities that discharge detectable levels of a pollutant into a water body where the pollutant is found in the fish tissue in the water body at levels exceeding the tissue basis of a Tier I criterion or Tier II value. EPA is proposing that all facilities that discharge detectable levels of this pollutant into the water body are contributing the pollutant and therefore meet the requirements of 40 CFR 122.44(d)(1)(i). Because fish are mobile and thereby reflect exposure over the entire water body, the fish tissue concentrations reflect the accumulated effect of all discharges. EPA invites specific comment on this provision of the proposal including whether the term "water body" should be defined in the final rule; any specific factors that should be considered in defining this term; and whether the scope of this provision should be limited to the definition of "same body of water" discussed as part of proposed procedure 5.E of appendix F to part 132 in the preamble above.

F. Whole Effluent Toxicity

1. Background

Today's preamble has focused, thus far, on the effect of individual pollutants on the water environment. In nature, pollutants are often not isolated; they are combined in effluents, and these effluents are, in turn, combined in receiving waters. Because the toxic effects of pollutants may change when they react with other pollutants, a focus on individual pollutants does not provide complete protection of water quality. Procedure 6 of appendix F of the proposed Guidance sets forth procedures for controlling the toxic effect of an effluent as a whole (known as "whole effluent toxicity" or "WET").

Concern for controlling the toxic effects of effluents is reflected in both the CWA and the Great Lakes Water Quality Agreement (GLWQA). Article II of the GLWQA and section 101(a) of the CWA provide that the discharge of toxics in toxic amounts should be prohibited. In addition, General Objective (d) of Article III of the GLWQA provides that water should be free from materials that will produce conditions that are toxic or harmful to human, animal or aquatic life. Pursuant to these goals, today's proposed procedure seeks to ensure that combinations of pollutants do not cause toxic effects.

The whole effluent approach to toxics control for the protection of aquatic life involves the use of acute and chronic toxicity tests to measure the toxicity of wastewaters. An acute test is defined as a test of 96 hours or less in which lethality or immobilization of aquatic organisms is the measured endpoint. A chronic test is defined as a long-term test in which sublethal effects, such as impaired fertilization, growth, or reproduction, are measured, in addition to lethality or immobilization. Aquatic organisms used in the tests include invertebrates, fish, and plants.

Terms commonly used to express the toxicity of an effluent include the lethal concentration (LC) and the no observed effect concentration (NOEC). The LC is the concentration of an effluent at which a certain percentage of test organisms die (for example, if 50 percent of the test organisms die in 20 percent effluent, the LC_{50}=20). The NOEC is the highest concentration of effluent that causes no observable adverse effects in the test organisms (for example, if none of the test organisms exhibit any adverse effects in 20 percent effluent, but some organisms exhibit adverse effects in 21 percent effluent, the NOEC = 20). Other commonly used terms are acute toxic units (TU_a) and chronic toxic units (TU_c), which are defined as follows:

$$TU_a = 100 / LC_{50}$$

$$TU_c = 100 / NOEC$$

For example, an effluent with LC_{50} = 20 translates to 5 TU_a's.

2. Current National Guidance

a. *Regulations.* EPA regulations define whole effluent toxicity as the aggregate toxic effect of an effluent measured directly by a toxicity test (40 CFR 122.2). EPA's authority to set limits on toxicity was upheld in *Natural Resources Defense Council Inc.* v. *EPA, 859 F.2d 156 (D.C. Cir. 1988).*

As discussed in section VIII.E of today's preamble, EPA's existing regulations require NPDES permits to include water quality-based effluent limitations (WQBELs) to control all pollutants or pollutant parameters, including WET, that the permitting authority determines are or may be discharged at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any water quality standards including numeric and narrative criteria for water quality (40 CFR 122.44(d)(1)). When determining whether a discharge will cause, have the reasonable potential to

cause, or contribute to an excursion above a water quality standard, a permitting authority must use relevant available data, including facility-specific effluent monitoring data where available. Additionally, a permitting authority must use procedures that account for existing controls on point and nonpoint sources of pollution; sensitivity of aquatic organisms; variability of the pollutant or pollutant parameter in the effluent; and, where appropriate, the dilution of the effluent in the receiving water (40 CFR 122.44(d)(1)(ii)).

If a permitting authority determines that a discharge causes, has the reasonable potential to cause, or contributes to an excursion of an applicable numeric water quality criterion for WET, it must include a WQBEL for WET in the permit (40 CFR 122.44(d)(1)(iv)). In the absence of a numeric water quality criterion for WET in a water quality standard, a permitting authority must derive an appropriate WQBEL for WET that will insure compliance with narrative criteria for water quality unless the permitting authority demonstrates that chemical-specific WQBELs are sufficient to attain and maintain applicable numeric and narrative water quality criteria (40 CFR 122.44(d)(1)(v)).

Current NPDES regulations at 40 CFR part 136 require permitting authorities to use analytical methods promulgated at 40 CFR part 136. In the case of WET, there are no promulgated analytical methods. When there is no analytical method promulgated, permitting authorities have the discretion to specify the method for use.

b. *Existing Technical Guidance.* EPA guidance on developing WQBELs for WET is set forth in the "Technical Support Document for Water Quality-based Toxics Control ("TSD")" (EPA/505/2–90–001, March 1991), which is available in the administrative record for this rulemaking. Copies are also available upon written request from the person listed in section XIII of this preamble. In the TSD, EPA provides recommendations on methods for, among other things, developing acute and chronic WET criteria from State or Tribal narrative water quality criteria, determining when a discharge has the reasonable potential to cause or contribute to an excursion above water quality standards, and conducting additional studies to identify the cause and method for treating WET. The TSD is EPA guidance only. It does not establish or affect legal rights or obligations.

Currently, there are no National water quality criteria for WET. In the TSD, EPA recommends that a State's narrative criterion be interpreted as 0.3 TU_a and 1.0 TU_c. Achievement of the criterion is measured with acute and chronic WET tests using at least three aquatic species. EPA also recommends in the TSD that the 0.3 TU_a and 1.0 TU_c values be applied as 24-hour and 4-day averages respectively, and that these values not be exceeded more than once every three years. These recommendations mirror the duration and frequency assumptions of EPA's National chemical criteria for protection of aquatic life.

The TSD explains the derivation of the 0.3 TU_a and 1.0 TU_c values. The 0.3 TU_a value represents the concentration that assures no lethality or mortality at any point within the ambient water column. EPA collected information on 496 acute 96-hour WET tests in the early 1980's which showed no mortality at the 0.3 TU_a level in 91 percent of the samples and used this information to support the recommendations in the TSD. The 1.0 TU_c value represents the highest concentration at which chronic toxicity effects are not observed throughout a waterbody.

In the TSD, EPA recommends applying the 0.3 TU_a acute criteria value at the edge of an acute mixing zone and the 1.0 TU_c chronic criteria value at the edge of a chronic mixing zone, unless otherwise prohibited by a State's water quality standards. (EPA interprets the CWA to give States the discretion to allow mixing zones in their water quality standards.) The TSD recognizes that in States that prohibit mixing zones, effluent limitations must assure that all State-adopted numeric criteria or interpretations of the narrative criterion are met within the discharge itself.

An acute mixing zone is a zone immediately surrounding a discharge point where neither acute nor chronic criteria need be met. (Acute mixing zones are also sometimes referred to as zones of initial dilution (ZIDs) or areas of initial mixing (AIMs). However, these terms may also have different regulatory definitions and may not be always used to denote an acute mixing zone.) A chronic mixing zone is where acute criteria must be met. All chronic criteria must be met at the edge of that zone. The TSD guidance also recommends that mixing zones be restricted in size in order to prevent impairment of the integrity of a waterbody.

The TSD guidance recognizes that permitting authorities have flexibility in assessing whether a discharge has reasonable potential to exceed water quality standards. For example, an authority may opt to use a stochastic dilution model that incorporates both ambient dilution and effluent variability rather than use a steady state dilution model with a statistically defined maximum effluent concentration. Also, a permitting authority may decide to develop a WQBEL in the absence of facility-specific effluent monitoring data. Whatever approach is selected by the authority, it must satisfy all requirements of 40 CFR 122.44(d)(1)(ii) summarized above.

Under EPA regulations, at least three outcomes are possible when deciding whether a facility causes, has the reasonable potential to cause, or contributes to an excursion above a water quality criterion. First, a permitting authority may determine that WET in a facility's discharge may be discharged at a level which causes, has the reasonable potential to cause, or contributes to an excursion above a narrative or numeric water quality criterion. In this case, EPA regulations require that the permitting authority establish a WQBEL in the permit. (40 CFR 122.44(d)(1)(i)) This WQBEL must be for WET, unless the permitting authority can demonstrate that chemical-specific limits are sufficient to attain and maintain applicable standards. (40 CFR 122.44(d)(1)(v))

Under EPA regulations and the TSD, reasonable potential is shown where an effluent, in conjunction with other point and nonpoint sources, is projected to cause an excursion above the water quality criterion. This projection is based upon an analysis of available data that accounts for, among other things, limited sample size and effluent variability.

Second, a permitting authority may have inadequate information to determine whether a discharge causes, has the reasonable potential to cause, or contributes to an excursion of a water quality criterion. In this case, EPA regulations do not require that the permitting authority establish a WQBEL, however, the TSD recommends that the permitting authority establish appropriate monitoring requirements and a reopener clause in the permit (see TSD at p. 60). A reopener clause authorizes "reopening" the permit and establishing additional permit conditions based upon monitoring results or other new factors that indicate that the effluent may cause, have the reasonable potential to cause, or contribute to an excursion above water quality standards. When permits are "reopened" in this manner, permitting authorities typically impose WQBELs for WET or require a discharger to perform a toxicity reduction evaluation (TRE).

Third, a permitting authority may determine that WET in a facility's discharge is not discharged at a level that causes, has the reasonable potential to cause, or contributes to an excursion above a water quality criterion. In this case, EPA regulations do not require that the permitting authority establish a WQBEL, however. The TSD recommends that effluent monitoring be repeated at a frequency of at least once every five years (see TSD at p. 60).

In the TSD, EPA also recognizes that permitting authorities may need to require permittees to take specific actions to identify the causes of exceedances of WET WQBELs. The TSD recommends that permitting authorities require permittees that are not in compliance with their WET WQBEL to use TREs to identify the causes of WET, isolate the sources of WET, evaluate the effectiveness of WET control options, and confirm the reduction of WET. EPA has published guidance for conducting TREs including "Generalized Methodology for Conducting Industrial Toxicity Reduction Evaluations (EPA/600/2–88/070)", "Toxicity Reduction Evaluation Protocol for Municipal Wastewater Treatment Plants (EPA/600/2–88/062)", "Methods for Aquatic Toxicity Identification Evaluations; Phase 1 Toxicity Characterization Procedures (EPA/600/3–88/034)", "Methods for Aquatic Toxicity Identification Evaluations; Phase 2 Toxicity Identification Procedures (EPA/600/3–88/035)", and "Methods for Aquatic Toxicity Identification Evaluations; Phase 3 Toxicity Confirmation Procedures (EPA/600/3–88/036)". which are available in the administrative record for this rulemaking.

EPA's guidance in the TSD recommends that TREs be required whenever a discharger exceeds a WET WQBEL and the effluent exhibits measurable WET more than 20 percent of the time. The recommendation in the TSD was based on the performance experience of EPA's research laboratory in Duluth, Minnesota which has successfully performed the toxicity identification evaluation step of a TRE on over 60 dischargers. If the discharge exhibits WET less than 20 percent of the time, the specific procedures of EPA's toxicity reduction evaluation guidance may be unable reliably to identify the cause of toxicity.

3. Great Lakes Guidance

Procedure 6 of appendix F of the proposed Guidance provides specific requirements for controlling the WET of discharges to the Great Lakes System. The procedure contains four sections: Discharge requirements for WET, appropriate test methods to measure WET, requirements for permit conditions, and reasonable potential procedures for determining whether or not limits for WET are necessary. The procedure does not cover all topics addressed in the TSD. The proposed Guidance on WET merely supplements, rather than replaces, the regulations at 40 CFR 122.44(d)(1) for dischargers to the Great Lakes System.

The requirements of procedure 6 of appendix F apply without regard to the cause of toxicity in an effluent. Specifically, these requirements apply whether or not one or more of the pollutants listed in Table 5 of part 132 of this Guidance is the cause or possible cause of toxicity in an effluent. As set in more detail elsewhere in this preamble, the rationale for not applying Implementation Procedures 1 through 5 and 7 through 9 to the Table 5 pollutants relates to fundamental inconsistencies between the nature of the pollutants and the specific requirements of the procedures. These considerations are not relevant with respect to procedure 6, which sets forth requirements with respect to the toxicity of effluents as a whole. A contrary viewpoint would seriously limit the effectiveness of the WET procedure since at least one of the Table 5 pollutants is likely to be present in the vast majority of discharges to the Great Lakes System.

a. *WET Basic Requirements.* Procedure 6.A of appendix F prohibits any discharge from: exceeding 1.0 TU_a at the point of discharge; causing or contributing to receiving water quality exceeding 1.0 TU_c (subject to certain exceptions); and causing or contributing to causing an excursion above any numeric WET criterion or narrative criterion for water quality within a State or Tribal water quality standard.

Procedure 6 does not require a Great Lakes State or Tribe to adopt numeric criteria for WET. The proposed Great Lakes Guidance, rather, specifies effluent restrictions that apply when either narrative or numeric criteria are involved. Like the Federal regulations at 40 CFR 122.44(d)(1) (iv) or (v), which provide for control of WET with either numeric or narrative criteria, respectively, the proposed Great Lakes Guidance allows the Great Lakes States or Tribes to choose the preferred form of criteria to implement. The proposed Guidance is at least as stringent as the Federal regulations.

The Technical Work Group of the Initiative Committees considered whether to require all Great Lakes States or Tribes to adopt numeric criteria for WET. This approach has the potential to ensure the greatest consistency when controlling WET. The Technical Work Group chose not to require the adoption of numeric criterion for WET due to a regulatory difference between implementation of numeric criteria and implementation of narrative criteria in existing Federal regulations. Under 40 CFR 122.44(d)(1)(v), permitting authorities may decide that WQBELs for WET are not necessary if the State's water quality standard does not contain a numeric criterion for WET and the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit that chemical-specific limits will be sufficient to prevent toxicity. This same discretion is not available for States that have a numeric criterion for WET in their WQS. To preserve this flexibility for the Great Lakes States, the Technical Work Group chose to structure procedure 6 in the manner set forth in the proposed Guidance. However, under proposed procedure 6, Great Lakes States and Tribes will be required to meet certain specific requirements in controlling WET whether the applicable water quality criteria are expressed in the narrative or numeric form. EPA believes that, under this procedure, discharge requirements for WET will be reasonably consistent among the Great Lakes States and Tribes.

EPA invites comments from the public as to whether the proposed Guidance should require Great Lakes States and Tribes to adopt numeric criteria for WET. In addition, if numeric criteria should be adopted, EPA is interested in receiving comments regarding what numeric criteria, including those specified in the TSD (0.3 TU_a and 1.0 TU_c), would be appropriate numeric criteria for WET.

i. *Acute Toxicity Control.* To protect against acute (short-term) effects in mixing zones, procedure 6.A.1 of the proposed Great Lakes Guidance proposes that no discharge exceed 1.0 TU_a. The 1.0 TU_a maximum limitation or "cap" is by definition no more than 50 percent mortality or immobilization in 100 percent effluent.

The 1.0 TU_a effluent cap is based upon the proposals of the Great Lakes Initiative Steering Committee. The Steering Committee believed that the 1.0 TU_a cap would protect water quality either as a single effluent limitation in water providing substantial dilution or in concert with a chronic WET limit in waters without substantial dilution. Whether a chronic limit is required to supplement a limit of 1.0 TU_a depends upon the amount of dilution that will occur in the receiving water. In waters

providing dilution of more than three times effluent flow, a 1.0 TU_a limit will be sufficient to attain and maintain the WET criteria recommended in the TSD (0.3 TU_a). (There is approximately a three-fold difference between the 1.0 and 0.3 TU_a values.) Indeed, in these situations, there is a possibility that a 1.0 TU_a may be overly stringent since, in these situations, the actual effect of the effluent in the receiving water, after dilution, may be less than 0.3 TU_a if the effluent is completely mixed after discharge. However, effluents in many of these situations actually form plumes and are not completely mixed for some distance downstream of the discharge. Discharge plumes can overlap such that the toxic effects of the effluent are compounded in the ambient water to the degree that the toxicity overwhelms the immediate aquatic life community. In addition, calculation of the WET concentrations at the edge of the plumes can pose an administrative burden in collecting the necessary dispersion information for conducting the calculations. For these reasons, the consensus of the Steering Committee was to propose an effluent cap of 1.0 TU_a.

The Steering Committee recognized that in discharge situations which provide dilution of less than three times the effluent flow, the 1.0 TU_a effluent limitation may not be stringent enough to insure that a narrative "no lethality" criterion, the 0.3 TU_a value or other approved numeric criterion for acute WET would be met. The reason for this lies in the definition of 1.0 TU_a as 100 times the reciprocal of the LC50. The LC50, as previously discussed in today's preamble, is the effluent concentration at which 50 percent of the exposed aquatic organisms demonstrate lethality or immobilization. In discharge dominated situations where the receiving water is comprised of a substantial fraction of the effluent, an effluent discharged at toxicity of 1.0 TU_a may not be sufficiently diluted to prevent lethality to organisms in the receiving water. In these situations, the appropriate control on toxicity should be based on the threshold at which acute toxicity occurs. The proposed Guidance uses effluent limitations on chronic toxicity as the means for accomplishing this. In contrast to the acute effluent limitation, the chronic effluent limitation is based on meeting a receiving water condition of 1.0 TU_c at the edge of the mixing zone, if such a mixing zone is allowed. The definition of 1.0 TU_c is the lowest effluent concentration at which no effects, including lethality or immobilization, are observed. It is a measure of the threshold of incipient toxicity. Therefore, for discharge scenarios with small amounts of available dilution, chronic testing should be performed and evaluated for unacceptable acute toxicity. When acute effects are measured, then a chronic limit based upon the level causing lethal effects should be imposed in addition to or in lieu of the 1.0 TU_a effluent cap.

The 1.0 TU_a effluent cap is consistent with the goal of the GLWQA at Annex 10, Part 3.(a)(i), where acute toxicological effects are prohibited. The GLWQA defines acute toxicological effects as whether the substance is lethal to "one-half of the test population of aquatic animals in 96 hours." Depending on the test species, the acute tests will last for either 48 hours (for invertebrates) or up to 96 hours (for vertebrates). Acute mixing zones would provide the basis for toxicity greater than 1.0 TU_a, and are therefore not part of the proposed Guidance.

EPA invites comment on the utility of other options for preventing acute WET effects in low dilution receiving water situations. In specific, EPA invites comment on the use of another acute WET testing endpoint, such as the LC_1 (effluent concentration at which 1 percent of the organisms demonstrate lethality or immobility) or a chronic toxicity test endpoint equivalent to 0.3 TU_a, either applied directly as an effluent limitation or as an ambient condition applied at the edge of the mixing zone. EPA also invites comment on whether the final Guidance should allow for acute mixing zones, and if so, what should be the maximum size.

In addition, EPA invites comment on the utility of other options for preventing acute WET effects in high dilution receiving water situations. In specific, EPA invites comments on whether the proposed effluent cap of 1.0 TU_a is too restrictive in high dilution situations, and if so, what effluent conditions would be fully protective of the narrative water quality criterion. In addition, EPA invites comment on the utility of an ambient criterion of 0.3 TU_a applied at the edge of an acute mixing zone for these situations, and on appropriate methods to calculate or estimate acute mixing zones.

EPA also invites comments on whether it would be appropriate to allow discharges with toxicity in excess of 1.0 TU_a where site-specific information is available to demonstrate that such discharges will not cause, contribute or have the reasonable potential to cause or contribute to an exceedance of a State or Tribal water quality standard.

ii. *Chronic Toxicity Control.* The proposed Guidance, at procedure 6.A.2 of appendix F, requires that a value of 1.0 TU_c must be maintained at all points of the receiving water except (i) within a mixing zone, or (ii) in any portion of the receiving water for which a permitting authority has demonstrated that due to the site-specific physical and hydrological conditions, it is unnecessary to apply any chronic WET requirements to protect aquatic life. The 1.0 TU_c value is, by definition, the point at which no effect is observed in a test solution that approximates the dilution of the effluent in the receiving water. This requirement is consistent with the TSD recommendation.

EPA invites comment on the ability of 1.0 TU_c applied at the edge of a chronic mixing zone to sufficiently achieve a State or Tribe's narrative water quality criterion. In particular, EPA invites comment on alternative definitions of 1.0 TU_c based on the use of a different chronic toxicity test endpoint (for example the IC_{25} endpoint). In addition, EPA invites comment on whether the 1.0 TU_c criterion should be adjusted higher or lower to reflect the sensitivity of aquatic organisms indigenous to the Great Lakes System.

Under procedure 6.A.2 of appendix F of the proposed Guidance, a Great Lakes State need not apply the 1.0 TU_c requirement (and therefore need not impose a chronic WET WQBEL) when a State demonstrates that due to local physical or hydrologic conditions of the receiving water, it is unnecessary to apply any chronic whole effluent toxicity requirements to protect aquatic life. This text is similar to that included in procedure 1 of appendix F, which provides that States may develop site-specific modifications to chronic aquatic life criteria/values for individual pollutants to reflect local physical or hydrologic conditions.

As explained in section VIII.A of this preamble, EPA believes that there may be sites within the Great Lakes System where, due to physical or hydrologic conditions, aquatic life will not remain for more than 96 hours. In such situations, WQBELs are not necessary to protect aquatic life from chronic impacts. Since the physical and hydrologic condition justification for the exception to procedure 6.A.2 of appendix F is functionally equivalent to a justification for the removal of a designated use at 40 CFR 131.10(g)(2), (4), and (5), EPA expects this exception will typically be used for waters where a full aquatic life use is unattainable. States must ensure that the application of this exception does not impair the water quality of downstream waters.

EPA invites comment on the ability of this exception to provide adequate protection of waters tributary to those waters where the exception may apply. In particular, EPA invites comment on the use of a 96-hour exposure period to define the waters where the exception applies and whether an alternative definition should be used.

iii. *Numeric and Narrative Criteria.* The proposed Guidance prohibits any discharge from causing or contributing to an excursion above any State or Tribe adopted numeric criteria for WET or interpretation of the narrative criterion for water quality. This provision was not contained in the Steering Committee's proposal. EPA added procedure 6.A.3 of appendix F to make it clear that the proposed Guidance on WET merely supplements, rather than replaces, the requirements of 40 CFR 122.44(d)(1) for dischargers into the Great Lakes System. EPA believes that procedure 6.A.3 is necessary because there may be instances where a Federally-approved State or Tribal water quality standard has additional or more stringent requirements pertaining to toxicity than those contained in today's proposal. Procedure 6.A.3 makes it clear that these additional requirements must still be met. EPA solicits comment on whether or not procedure 6.A.3 of appendix F is a necessary or appropriate part for the proposed Guidance.

b. *WET Test Methods.* Procedure 6.B. of appendix F of the proposed Guidance requires all WET tests be performed in accordance with test procedures approved under 40 CFR part 136. Current NPDES regulations at 40 CFR part 136 require permitting authorities to use analytical methods promulgated at 40 CFR part 136. In the case of WET, there are no promulgated analytical methods. When there is no analytical method promulgated, permitting authorities have the discretion to specify the method for use. The proposed Guidance at procedure 6.B is consistent with this current NPDES requirement.

Although EPA has yet to approve any analytical methods for WET under 40 CFR part 136, EPA expects to do so before the proposed Great Lakes Water Quality Guidance is finalized. Until such methods are approved, permitting authorities have the discretion under procedure 6.B to choose appropriate analytical methods.

EPA expects that permitting authorities, in exercising this discretion, will require WET analytical methods that include conditions such as the test species to be used in tests, length of exposure for both acute and chronic test procedures, conditions of the effluent and control water solution, appropriate methods for evaluating the data, and reporting requirements.

EPA invites comment on the WET test methods that should be identified in the final Great Lakes Water Quality Guidance. In addition, EPA invites specific comment on what factors a permitting authority should consider in approving any particular test, and whether consideration of such factors should be required in the final Guidance.

c. *Permit Conditions.* The proposed Guidance proposes specific permit requirements for each of three situations. These are:

(1) When sufficient data demonstrate that the reasonable potential to violate the requirements of procedure 6.A of appendix F exists;

(2) When sufficient data are not available to determine whether the discharge has the reasonable potential to violate the requirements of procedure 6.A; and

(3) When adequate data demonstrate that reasonable potential to violate the requirements of procedure 6.A does not exist.

i. *Data Indicates the Reasonable Potential for WET.* Procedure 6.C.1 of appendix F requires that permitting authorities impose effluent limitations for WET when sufficient effluent-specific data demonstrate, in accordance with procedures 6.D.2 or D.3, that the reasonable potential exists to violate the requirements of procedure 6.A. Procedure 6.C.1. also includes three other provisions:

(1) Chronic WQBELs shall be calculated based upon the dilution calculations specified in sections C and D of procedure B3 of appendix F;

(2) A schedule of compliance consistent with procedure 9 of appendix F of the proposed Guidance may be included in the NPDES permit; and

(3) When regulating using a narrative criterion for water quality, a specific WQBEL for WET may not be necessary if it can be shown (and documented in a fact sheet or statement of basis for a NPDES permit) that chemical-specific WQBELs will ensure compliance with the requirements of procedure 6.A.

When reasonable potential exists, the effluent limitations for acute WET will be equal to, or less than, 1.0 TU_a. The effluent limitations for chronic WET will be derived using the equation specified in procedure B3.C.2.a of appendix F for lake discharges or the Q_{ad} developed for the discharge using the requirement in procedure B3.D.3.a.ii for tributary discharges. These specific procedures from procedure B3 calculate the effect of dilution in establishing an effluent limitation that achieve a criterion at the edge of the mixing zone. EPA believes that these dilution considerations that were developed to apply to specific pollutants also apply to WET. EPA invites specific comment on the use of these procedures for WET, and if not appropriate, suggestions on what alternative procedure should be included in the final Guidance.

EPA expects that the WQBELs for WET will be compared for compliance purposes to all species tested. EPA invites comments on whether it is necessary to provide specific requirements to meet the most sensitive species.

Because some existing dischargers may not be able to meet WET limits at the time that their permits are reissued or modified to include new WET limits, EPA believes that allowing some permittees time in which to achieve compliance may be appropriate where allowed for in State or Tribal water quality standards. The proposed Guidance requires that compliance schedules, however, be developed in accordance with procedure 9 of appendix F of the proposed Guidance. EPA invites comment of this provision in conjunction with the comments on procedure 9.

The provision at procedure 6.C.1.d mirrors the existing regulation at 40 CFR 122.44(d)(1)(v). As discussed earlier, EPA is including this provision to eliminate any confusion about the applicability of 40 CFR 122.44(d)(1)(v) to facilities covered by the Guidance.

ii. *Insufficient Data to Determine the Reasonable Potential for WET.* As previously discussed in this preamble, 40 CFR 122.44(d)(1)(i) requires a permitting authority to impose effluent limitations whenever it finds that a facility has the reasonable potential to cause or contribute to an excursion above a State's numeric or narrative water quality criterion. Procedure 6.C.2 of the proposed Guidance recognizes the potential for a permitting authority to have insufficient information reliably to determine whether a facility causes, has the reasonable potential to cause, or contributes to such an excursion. In this instance, the proposed Guidance requires permitting authorities to collect sufficient information by requiring effluent monitoring in permits.

The Technical Work Group recognized the necessity to make permitting decisions based on good information and the preference for facility-specific effluent monitoring data for making these decisions. The Technical Work Group considered several ways in which to collect such information. One approach is to collect

the necessary information as a permit monitoring condition. In this approach, the permitting authority would impose specific WET monitoring requirements that reflect the site-specific factors of the facility. This approach allows the permitting authority to gather information that is representative of the effluent condition over a multiple-year period, and therefore the effluent's variability can be reasonably assessed. In addition, this approach allows the permitting authority to tailor the requirements for sample collection to the specific instances of the facility based on the information in the permit application. However, this approach does delay the determination of reasonable potential to the next permit reissuance action which may be five years later.

Another approach is to require sufficient information as part of the permit application process. In this approach, the permitting authority would require the facility to collect the necessary WET monitoring information prior to permit issuance. This approach has the advantage in providing the necessary information to make reasonable potential determinations before the first permit reissuance. However, there may not be sufficient time to collect such information prior to permit issuance nor may the permitting authority know of all site-specific factors that it may need to appropriately determine the monitoring conditions.

A third approach is for the permitting authority to collect the necessary information itself prior to permit issuance. This approach has the same advantages and disadvantages as requiring facilities to submit WET monitoring information with the permit application. It also has the additional disadvantage of imposing a large resource burden on States due to the need to send inspectors to each facility to collect the information.

The Technical Work Group proposed the alternative of requiring effluent monitoring as a permit condition. This proposal is also consistent with EPA's guidance (TSD at page 60). The proposed Guidance does not identify the type of facility required to collect this information, nor the amount and type of effluent monitoring data that would comprise a sufficient set of information. The proposed Guidance reserves the existing discretion of permitting authorities to make these decisions based on the site-specific characteristics of the facility and its receiving water. In deciding what facilities are required to collect effluent WET monitoring data, permitting authorities may consider a number of factors including the type of facility, the potential sources of toxic contaminants, the presence of individual toxic pollutants in the effluent, and known impacts on the receiving water. In deciding the type of monitoring that comprises a sufficient data set, EPA expects permitting authorities to require WET tests using multiple aquatic species to be consistent with the provision of 40 CFR 122.44(d)(1)(ii) that requires consideration of aquatic species sensitivity. The amount of information is left entirely to the discretion of the permitting authority; the means to account for the uncertainties posed by infrequent monitoring are addressed in the discussion of procedure 6.D of appendix F of part 132 in today's preamble.

Recognizing that the approach of collecting effluent monitoring data as a permit condition could delay effluent controls necessary to achieve State numeric and narrative water quality criteria, the Technical Work Group also proposed that such effluent monitoring be combined with a permit requirement that the permittee initiate a TRE if the monitoring demonstrated the reasonable potential. The effluent conditions necessary to initiate a TRE are not specified in the proposed Guidance; again, permitting authorities retain the discretion to make these decisions based on the site-specific characteristics of the facility and its receiving water.

EPA invites comment on this proposed approach, and/or whether any alternatives should be included in the final Guidance. In particular, EPA invites comment on whether the final Guidance should require specific monitoring conditions such as the minimum number of samples to be collected, the type of WET tests (acute or chronic, and which species), and which facilities need effluent WET monitoring as a permit condition. EPA also invites comment on whether a TRE should be required as a permit condition if the effluent monitoring demonstrates reasonable potential, and whether the final Guidance should include a specific condition that requires initiation of a TRE. EPA would also like comment on whether procedure 6 of appendix F should require a specific reopener clause for WET as opposed to or in addition to the TRE requirement mentioned above.

iii. *Data Indicates No Reasonable Potential for WET.* Procedure 6.C.3 of appendix F restates the current authority for a permitting authority to establish monitoring requirements for WET in an NPDES permit. The permitting authority may decide that it is appropriate to impose continued testing conditions upon those dischargers for which it does not find the reasonable potential to exceed numeric or narrative water quality criteria. Where the permitting authority concludes that a continued monitoring requirement is warranted based upon the particular circumstances of a discharge, the permitting authority may require continued testing for a reasonable period of time and then evaluate the monitoring results at the conclusion of this period. For example, a permitting authority may decide to impose continued monitoring for a discharger for which available effluent WET data are limited or for which more recent information raises the specter of reasonable potential. Under sections 308 and 402 of the CWA, a permitting authority can require NPDES permittees to provide WET testing data to assure compliance with State or Tribal water quality standards.

d. *Reasonable Potential Determinations.* The proposed Guidance specifies how a permitting authority shall determine the reasonable potential to exceed the condition of procedure 6.A of appendix F. These specific procedures are similar to those of procedure 5 of the proposed Guidance which pertains only to individual pollutants.

The proposed Guidance requires that the factors described in 40 CFR 122.44(d)(1)(ii) be evaluated when making a determination whether reasonable potential to violate procedure 6.A of appendix F exists. These factors need to be considered in all evaluations because the conditions of 40 CFR 122.44(d) require that when the reasonable potential to exceed State water quality standards exists, a limit must be imposed into a permit. The conditions for evaluating reasonable potential are not limited to situations where effluent-specific data are available. The regulatory factors which apply to WET and need to be evaluated are: accounting for existing controls on the point and nonpoint sources of pollution, the variability of the pollutant parameter in the effluent, the sensitivity of the species to toxicity testing and where appropriate the dilution of the effluent in the receiving water.

The first factor in 40 CFR 122.44(d)(1)(ii) requires that existing controls on point and nonpoint sources must be evaluated. States must ensure that existing controls on adjacent discharges and the discharge of interest, as a whole, maintain the in-stream water quality requirements for acute and chronic WET. If the total controls cannot ensure that the WET requirements will be attained and

maintained, then additional controls need to be required in one or all cases. Existing State procedures also need to be used to account for multiple dischargers or toxicity from upstream sources.

Procedure 6 applies for the most part when facility-specific effluent data are available. However, there are situations when a permitting authority may determine without facility-specific effluent data that the reasonable potential to cause an excursion of a WET criterion or the narrative criterion exists. Effluent data from similar industrial operations can be used to evaluate a facility for which no effluent-specific data exist. This information, within the judgement of the permitting authority can be used as a basis for evaluating whether the reasonable potential to violate the WET requirements exists.

When effluent data are available, procedures 6.D.1, D.2 and D.3 of appendix F also apply. It is believed that the procedures set forth in procedures 6.D.1, D.2 and D.3 incorporate most of those factors to some extent. There may be some situations, however, where those formulas, themselves, do not involve all of the evaluating factors from 40 CFR 122.44(d)(1)(ii). In those situations, the additional factors must be considered.

i. *Characterizing Acute and Chronic Toxicity Values.* Great Lakes Guidance for determining the reasonable potential to cause or contribute to a violation of State water quality standards for toxicity is provided in procedure 6.D or appendix F. (The Great Lakes Guidance for assessing reasonable potential to cause or contribute to water quality standards violations of chemical-specific numeric criteria is included in procedure 5 of appendix F, which was discussed in section VIII.E. of this preamble.) Procedure 6.D.1 provides guidance for three areas: how to characterize effluents when more than one toxicity result is available for a given time period; how to evaluate toxicity results for different test species; and how to predict either chronic or acute toxicity levels if only one of the types of toxicity results are available.

If several acute tests are performed on an effluent discharged on a given day or several chronic tests are performed during a given month, procedures 6.D.1.a and 1.b recognize that averaging the data for the same species is appropriate. When only one WET test sample is collected, it is generally considered representative and the most toxic result for each species is used to determine if an effluent causes, has the reasonable potential to cause or contributes to a violation of the requirements in procedure 6.A. However, due to the possibility that multiple tests may be conducted during the same day for acute tests or the same month for chronic tests, the proposed Guidance provides additional guidance.

Acute test results generally equate to one day maxima, and therefore the proposed Great Lakes Guidance proposes that all acute tests for the same species collected during one contiguous 24-hour period will be averaged to give one daily result. Similarly, since chronic test results in the existing Great Lakes State NPDES programs generally equate to monthly average concentrations, all chronic tests taken during the same calendar month for the same species will be averaged to give one monthly result. The acute and chronic averages will be used in the comparison provided in procedure 6.D.2 and procedure 6.D.3, respectively, to determine the need for a limit.

The regulations at 40 CFR 122.44(d)(1)(ii) require that species sensitivity be taken into account when determining whether the reasonable potential to exceed water quality standards exist. Species sensitivity occurs because aquatic species react differently to the causes of the toxicity in an effluent. In order to address this potential for variation and to be consistent with the regulatory requirements, the proposed Guidance at procedures 6.D.1.a and 1.b of appendix F provides explicit direction to average only test results which are for the same test species. If the results from a sensitive species were averaged with a less sensitive species, the average would mask the worse case toxicity levels for the most sensitive species. The "average" results for each species along with other available effluent data will be used in the reasonable potential determinations provided in procedures 6.D.2 or D.3.

The provision in paragraph D.1.c of procedure 6 of appendix F provides the guidance for a State or Tribe to predict chronic toxicity from acute toxicity results or acute toxicity from chronic toxicity results, if one of the types of toxicity test results are not available. It is not unusual to have only one type of test, i.e. either acute WET tests or chronic WET tests, for a particular effluent. The acute-to-chronic ratio (ACR) expresses the relationship between the concentration of WET, or a toxicant causing acute toxicity to a species, and the concentration of WET, or a toxicant causing chronic toxicity to the same species. An ACR is commonly used to extrapolate to a chronic toxicity concentration using exposure considerations and available acute toxicity data when chronic toxicity data for the effluent are not available. This is often used in order to reduce testing costs. The ACR is ideally calculated using effluent-specific acute and chronic test results. In the absence of data to develop a facility-specific ACR, the TSD suggests that an ACR of 10 is an appropriate default. The default ACR is the upper 90th percentile of all the ACR data presented in appendix A–3 of the TSD. Given the protective margin of safety inherent with the use of a critical flow for the calculation of a chronic receiving water concentration, an ACR of 10 should provide ample protection against chronic instream impacts.

The proposed Guidance states that effluent-specific ACRs shall be used where available. Gathering enough data to develop an effluent-specific ACR can be costly and may be unnecessary to characterize an effluent. The proposed Great Lakes Guidance, consistent with National guidance, allows the use of effluent specific ACRs, and in the absence of effluent specific ACR, the use of a default ACR of 10. EPA invites comments on whether other values above or below 10 would be more suitable for default ACRs. EPA would be interested in receiving comment on the alternative numbers and the justification for those alternative ACRs.

ii. *Specific Conditions for Acute Toxicity.* The Great Lakes Guidance for WET also contains specific requirements for determining the reasonable potential to exceed the conditions of procedure 6.A of appendix F when effluent data are available. Procedure 6.D contains the reasonable potential requirements for WET which are equivalent to procedure 5 for chemical-specific criteria. Procedures 6.D.2 and D.3 provide customized requirements for determining the reasonable potential to violate the WET requirements in procedure 6.A for acute and chronic WET effects, respectively. Specifically for acute toxicity, reasonable potential exists if the results from an acute WET test divided into 50 percent is less than a factor that accounts for effluent variability and the number of effluent samples collected.

These factors were calculated using a 95 percent confidence level and a 95 percent probability basis. The factor is applied to account for uncertainties and variability with the effluent data. As mentioned above, this is a function of the number of samples and the coefficient of variation of the effluent samples. Because of the uncertainty in deriving a CV for data sets with less than 10 data points, the CV is assumed to be 0.6. For data sets with 10 or greater

samples, the CV shall be calculated by determining the standard deviation of the values and dividing by the mean.

The term "individual WET tests" means any results of acute WET tests derived from samples taken on a particular day when no other test results are available for the same day, and the average of results, derived in accordance with procedure 6.D.1.a, when more than one sample was taken on a particular day. The samples used in averaging results for a day, would not be accounted for in the number of samples for determining the CV. For example, a permittee may have eight acute test results of samples taken on 8 separate days. In addition, a sample was split between the permittee and EPA during an inspection on another day. Assuming that both results of the split sample meet the appropriate quality assurance goals, both shall be averaged and the results treated as one sample and one result, in accordance with the guidance at procedure 6.D.1.a. In order to determine whether effluent has the reasonable potential according to procedure 6.D.2, the CV would be based upon a sample of 9 results and not 10 results.

The equation at procedure 6.D.2 provides a concise formula with which to determine whether the reasonable potential exists to violate the 1.0 TU_a effluent cap and therefore violate any narrative criterion for water quality or numeric criterion for acute WET. The equation is based upon the discussion provided in the TSD for determining whether reasonable potential exists. This equation and the premise in the TSD is to statistically estimate the greatest level of WET that could exist in a particular effluent. A statistically derived factor is applied to the highest WET level based upon actual effluent data. The resultant would then be the estimate of the highest possible level of acute WET that could be reasonably expected in the effluent.

This procedure is consistent with that specified in procedure 5 of the proposed Guidance. The preamble discussion at section VIII.E.2.b.i provides a thorough explanation of the justification for this statistical approach used in both procedures. The equation has been modified for acute toxicity, to relate to the TSD recommendations with the basic policy of the Steering Committee of no acute mixing zones beyond 1.0 TU_a, the criterion will equal 50 percent without accounting for additional receiving water flow. The expression of the process has been placed in equation format for the proposed Great Lakes Guidance.

Comments on the basic statistical approach should address the discussion provided in the preamble discussion for procedure 5 of appendix F. EPA invites comments, however, regarding whether the application of this reasonable potential procedure is appropriate for acute WET.

iii. *Specific Conditions for Chronic Toxicity.* The reasonable potential determination for chronic toxicity is similar to the discussion for acute toxicity. The proposed Great Lakes Guidance formula for determining whether reasonable potential to exceed the 1.0 TU_c requirement is that reasonable potential exists if the level of chronic toxicity of the effluent is greater than the reciprocal of the product of a multiply factor and the receiving water concentration (RWC) of the effluent. Again, the size of the data sets dictates the CV that is used in selecting the multiplying factor. In addition, the dilution flow from the receiving water is taken into account. The dilution flow is calculated using the guidance from procedure B3.C for lake dischargers and procedure B3.D for tributary dischargers.

The proposed Great Lakes Guidance provides additional requirements when deriving the appropriate amount of dilution which should be used in developing the RWC. The RWC is based upon the dilution of the effluent in the receiving water. For tributary discharges, the RWC is calculated differently if the entity uses the receiving water for any portion of its process wastewater. For entities which do not use the receiving water for the source water, the RWC is the source flow divided by the sum of the Q_{7d} derived using procedure B3 of appendix F plus the effluent flow. For entities which use the receiving water for some or all of its source water, the RWC is derived by dividing the effluent flow by the Q_{7d}. The RWC for lake discharges is the effluent flow divided by 11.

When the RWC is high and the coefficient of variation is great, the formula will calculate chronic effluent levels that cannot be measured. For the situations where B is greater than 1/RWC, the proposed Great Lakes Guidance provides flexibility for the State to review the raw chronic toxicity results to determine whether or not the discharge has the reasonable potential to exceed the 1.0 TU_c level.

This formula is consistent with the guidance provided in the TSD, section 3. The proposed Great Lakes Guidance recommends estimating an upper bound of the amount of toxicity which would be allowed in the receiving water based upon the available dilution. If the chronic test results exceed the upper bound estimate of what can be discharged, then the effluent has the reasonable potential to cause an excursion above the numeric chronic WET requirement.

EPA invites comments on whether this approach is appropriate for determining the reasonable potential to exceed the chronic WET requirements of procedure 6.A of appendix F.

e. *State and Tribal Adoption of Guidance.* Section 132.4(a)(7) of the proposed Guidance requires Great Lakes States and Tribes to adopt procedures that are consistent with the proposed Great Lakes Water Quality Guidance. Great Lakes States and Tribes shall adopt procedures for deriving permit limits to control WET that are consistent with procedure 6 of the Implementation Procedures of appendix F of the proposed Guidance. Procedure 6 of the proposed Guidance is intended to implement both narrative and numeric criteria for toxicity. In the event a Great Lakes State or Tribe chooses to regulate WET through narrative water quality criteria, those criteria may not be implemented in any manner less stringent than specified in the proposed procedure. In the event a Great Lakes State or Tribe chooses to regulate WET through numeric water quality criteria, those numeric criteria must be sufficiently stringent to provide a basis for requiring all dischargers to comply with the terms of procedure 6.A of appendix F.

In addition, a Great Lakes State or Tribe must adopt procedures that, at a minimum, require consideration of the same types of information as specified in the proposed procedure 6.D of appendix F and reach a decision that an effluent limit is necessary where the proposed procedures 6.D.2 and D.3 require effluent limitations.

G. Loading Limits

1. Expression of WQBELs as Concentration and Mass Loading Rates

In the proposed Guidance, EPA is proposing to require that water quality-based effluent limits (WQBELs) for all pollutants discharged to the Great Lakes System be limited in NPDES permits in terms of concentration and mass loading rate, except for those which cannot appropriately be expressed in terms of mass. These requirements are intended to clarify what EPA believes to be the appropriate application of the existing Federal regulations at 40 CFR 122.45(f) to the Great Lakes System to most effectively implement the objectives of the Clean Water Act and GLWQA.

The unique character of the Great Lakes System is the basis for the proposed requirement that WQBELs be expressed in terms of both concentration and mass loading rates. Because of the long retention time and the complex flow patterns of the water in the Great Lakes System, the Lakes tend to act as a sink, accumulating persistent pollutants discharged to them. Many of the lingering contamination problems in the Great Lakes System are the result of the long-term build-up and slow elimination rate of persistent contaminants in the System. These characteristics are discussed in Background sections I.A and I.D of the preamble. During deliberations on the proposed Guidance, the Great Lakes States proposed inclusion of a provision requiring the expression of WQBELs as both concentration and mass loading rate values to protect the integrity of the Great Lakes System. In particular, concerns were expressed that increased loads of pollutants, which might comply with concentration limits, could accumulate in the Great Lakes System and result in increased difficulty in attaining the goals and objectives of the Clean Water Act, the GLWQA and the Great Lakes Governors' Toxics Agreement. The Great Lakes States were concerned that any additional accumulation of these chemicals in the Great Lakes System could prevent the attainment of beneficial uses.

EPA shares these concerns and believes that the use of mass loading rate limitations is appropriate to implement the general purpose of the GLWQA to restore and maintain the chemical, physical and biological integrity of the waters of the Great Lakes Basin Ecosystem. In order to achieve this purpose, the Governments of the United States and Canada agreed in the GLWQA to establish programs to eliminate and reduce to the maximum extent practicable the discharge of pollutants into the Great Lakes System. (Article II). The Governments also agreed that, consistent with these provisions of the GLWQA, it is the policy of the United States and Canada that "the discharge of toxic substances in toxic amounts be prohibited and the discharge of any or all persistent toxic substances be virtually eliminated." (Article II(a)). Additionally, the United States and Canada agreed that all reasonable and practicable measures must be taken to maintain and improve the existing water quality in those areas of the boundary waters of the Great Lakes System where such water quality is better than that prescribed by Specific Objectives and in those areas having outstanding natural resource value. (Article IV(c)). The proposed requirement to establish both concentration and mass-based WQBELs in permits for discharges of pollutants to the Great Lakes System will help to assure progress toward these goals and objectives.

The existing Federal regulations at 40 CFR 122.45(f) require, with several limited exceptions, the establishment of mass loading limitations in NPDES permits. The following discussion compares the requirements in the proposed Guidance to the existing regulation, with emphasis on the exceptions in the existing regulation.

First, the proposed Guidance provides one exception from the requirement to express WQBELs in both concentration values and mass loading rates. Consistent with the existing Federal regulations at 40 CFR 122.45(f)(1), the proposed Guidance does not require Great Lakes States to express WQBELs as mass loading rates for pollutants which cannot be appropriately expressed in terms of mass, such as pH, color, temperature, or radiation.

Second, the Federal regulation also includes an exception to the requirement for the development of mass-based WQBELs for pollutants for which technology-based limits, developed on a case-by-case basis using 40 CFR 125.3, cannot feasibly be expressed in terms of mass. Because the proposed Guidance does not apply to technology-based limits, it does not affect the application of this provision of the Federal regulations.

Third, the proposed Guidance does not include the exception from mass limits in 40 CFR 122.45(f) for pollutants for which applicable standards or limitations are expressed in terms of other units of measurement. Based on this exception, permitting authorities are not currently required to establish mass loading rate WQBELs in all NPDES permits if, for example, the applicable water quality standards are expressed only in terms of concentration in the ambient water. Although 40 CFR 122.45(f) does not require establishment of mass loading limits in all permits under these circumstances, the permitting authority must, however, currently include any limits determined necessary based on best professional judgment to meet water quality standards, including, where appropriate, mass loading rate limits. (CWA sec. 301(b)(1)(c); 40 CFR 122.44(d).)

The proposed Guidance is consistent with existing EPA guidance supporting the use of mass loading rate limitations to protect water quality under these circumstances. The March 1991 revised "Technical Support Document for Water Quality-based Toxics Control (TSD)", which is available in the administrative record for this proposed rulemaking, provides EPA's current nationwide guidance on the implementation of the statutory requirements of section 301(b)(1)(C) of the Clean Water Act and the associated Federal regulations, specifically 40 CFR 122.44(d)(1). Copies of this document are also available upon written request from the person listed in section XIII of this preamble. The TSD explicitly addresses the expression of WQBELs in terms of mass loading rates. Section 5.7.1 of the TSD clarifies that mass loading rate limitations are especially important for the control of bioconcentratable pollutants or those pollutants with effluent concentrations that are below detection levels. It further supports the complementary use of concentration limits and mass limits, particularly in low dilution situations. (See also 49 FR 38031, September 26, 1984, "Permit writers are encouraged to express limits in terms of both mass and concentration. Mass-based limits are necessary and encouraged to prevent the use of dilution as a means of treatment and also, where water quality is limiting, control total loadings in regard to the assimilative capacity of the receiving water body.")

Finally, the proposed Guidance to express WQBELs as both concentration values and mass loading rates is necessary to implement the proposed antidegradation policy for the Great Lakes System. The use of mass limits in the Great Lakes antidegradation analysis is discussed in appendix E of the proposed Guidance.

For the reasons identified above, EPA believes that WQBELs for discharges to the Great Lakes System should be established as both a concentration value and an equivalent mass loading rate. EPA requests comment on all aspects of procedure 7 of appendix F of part 132 including whether the requirement to establish WQBELs as both concentration values and mass loading rates should be limited to an identified class of pollutants, (e.g., persistent or bioaccumulative pollutants) and identification of any alternative provisions to achieve the goals of the CWA, GLWQA, and the Great Lakes Governors' Toxics Agreement.

2. Procedures to Calculate Mass Loading Limits

Proposed procedure 7 of appendix F establishes procedures to calculate mass loading rate effluent limitations to

restrict the loadings of pollutants to the Great Lakes System. As discussed above, procedure 7 requires that when a WQBEL is developed based on procedures 3, 5, or other State procedures, the limitation must be expressed in terms of both concentration and mass loading rate.

Proposed procedure 7 also requires that the concentration and mass limitations must be consistent in terms of daily, weekly, and monthly averages, or in other appropriate time-related terms. (procedure 7.A). For example, where a concentration-based WQBEL is expressed in terms of maximum daily and average monthly limitations, the corresponding mass loading rate limitations must likewise be expressed as maximum daily and average monthly limitations. The existing Federal regulation at 40 CFR 122.45(d) requires that limitations for continuous discharges be expressed, unless impracticable, as average weekly and average monthly limitations for POTWs and maximum daily and average monthly limitations for all other continuous discharges. The proposed Guidance does not change these existing requirements, but instead ensures consistency between mass and concentration-based limitations in individual NPDES permits.

During the Initiative Committee's deliberations on the proposed Guidance, an alternative was considered regarding the use of averaging periods for WQBELs that are based on the criterion that the limits were derived to protect. Under such an alternative, WQBELs would be expressed in terms which are consistent with the duration of the criterion/value upon which the limitations were based. For example, WQBELs based upon acute aquatic life criteria would be expressed only as daily maxima. Similarly, it would be acceptable under such an approach to express WQBELs based on human health criteria as only annual averages because the human health criteria are derived using long-term exposure assumptions. This approach, however, appears is inconsistent with the existing NPDES regulations for continuous discharges at 40 CFR 122.45(d). The existing regulation allows deviations from the standard application of daily maxima or weekly averages, and monthly averages only in cases where deriving such limitations is impracticable. EPA's guidance provided in the TSD provides the mechanism in most circumstances to derive daily maximum, weekly average, and monthly average limitations, regardless of the criterion, as is required by the existing regulation. EPA welcomes comment on all aspects of procedure 7.A of appendix F, including the identified alternative, other alternatives, and the practicability of implementing the proposed approach. EPA also requests comment on whether only requiring that mass loading limitations be expressed as monthly averages, in combination with the appropriate concentration limits which would still be required to fully implement 40 CFR 122.45(d), would adequately implement the objectives of the CWA and GLWQA for the Great Lakes System. As discussed below with regard to wet-weather discharges, such an approach may be appropriate to address short-term effluent mass discharge variability that may be associated with wet weather.

Proposed procedure 7.B of appendix F directs the permit writer to use effluent flow rates when developing the mass loading rate limits that are consistent with those used in procedures 3, 5, or other State procedures, to develop the concentration-based WQBELs. For example, under procedure 3 of appendix F, a specific effluent flow rate and a receiving water flow rate will be utilized for each pollutant to determine the TMDL and WLA, and from them the WQBEL, that will protect the water quality standards (WQS) in the receiving water. Under the requirements of procedure 7.B, an effluent flow rate that is consistent with that used in the foregoing process to derive a concentration-based WQBEL for a pollutant would be applied to derive the mass loading rate limitation. The existing Federal regulations at 40 CFR 122.44(d)(1)(vii)(B) and 123.25(a)(15) require that water quality-based effluent limits in State and Federal NPDES permits be "* * * consistent with the assumptions and requirements of any available wasteload allocation for the discharge * * *". By specifying this requirement in today's proposal, EPA believes that it will eliminate confusion that might arise regarding the proper effluent flow rate to be used in development of mass loading rate permit limitations and thereby ensure greater consistency between WQBELs in the Great Lakes System.

During the deliberation process on the proposed Guidance, EPA and the Great Lakes States considered requiring permitting authorities to use design flows for POTWs and annual average flows for industrial facilities in all circumstances to calculate mass loading limitations as an alternative to proposed procedure 7.B. These flows are used as default values by some Great Lakes States in establishing WQBELs and may have the beneficial effect of providing a consistent requirement applicable to all WQBELs in a permit, rather than requiring the development of differing effluent flow rates to correspond to different criteria. EPA is not proposing this alternative in the proposed Guidance, because EPA believes that it is more appropriate to ensure that the permitting authority retains the flexibility in establishing effluent flow rates to adequately account for effluent variability. EPA welcomes comment on all aspects of procedure 7.B, including the identified alternative or other alternative procedures.

3. Special Provisions Applicable to Wet-weather Discharges

During Technical Work Group deliberations on the proposed Guidance, EPA and the Great Lakes States considered including specific provisions in the loading limits procedure to address elevated effluent flows from continuous discharges that might occur during wet-weather discharge events. EPA is not proposing such text in the proposed Guidance because it believes that the procedures for development of TMDLs and WLAs, and from them WQBELs, already provide the permitting authority with the ability to adequately account for effluent variability in continuous discharges, including that resulting from wet-weather events. EPA invites comment on this conclusion and on the provisions discussed below, which were considered by the Technical Work Group.

During Technical Work Group deliberations on the proposed Guidance, concerns were expressed regarding the increased discharge flow rates that might be associated with wet weather, and their effect on compliance with mass loading rate limitations. Specifically, it was argued that if wet-weather events increase the flow rates from certain point source discharges, the potential to exceed mass loading rate limits may also increase if the wet-weather portion of the discharge carries any of the limited pollutants. In contrast, it was argued that wet weather will generally not pose a similar concern for compliance with concentration limits, as the wet-weather component of a discharge will typically be dilute even when it may be contaminated with the limited pollutant. Furthermore, the effect of the wet-weather discharges on the receiving water may be more complicated as nonpoint contributions may increase and the resulting ambient pollutant concentrations may increase or decrease. The effect of wet weather on compliance with WQS is discussed more thoroughly elsewhere in the

proposed Guidance. To account for the perceived uncertain effect on water quality of increased wet-weather mass loading rates and potential for permit limit violations, the Technical Work Group considered a procedure that would have allowed the permitting authority to establish special permit conditions associated with wet-weather mass loading rates for non-BCC pollutants as long as such loading rates would still result in the attainment of the applicable water quality criteria. The provision would have been limited to non-BCC pollutants because of the overriding concerns, discussed above, associated with long-term mass loadings of BCC pollutants.

EPA is not proposing to include specific provisions in the loading limits procedure to address wet-weather flows, because it believes that effluent variability, which such a provision would seek to address, may already be adequately addressed on a case-by-case basis by the permitting authority. Effluent variability is already a required consideration in determining if WQBELs are necessary to protect water quality (40 CFR 122.44(d)(1)(ii)), and EPA's TSD provides EPA's guidance on how effluent variability should be addressed in WQBEL development. Permitting authorities continue to have the ability to account for effluent variability, even though the proposed Guidance on loading limits provides no specific provisions for addressing wet-weather flows. Furthermore, EPA is not aware of information showing that the risk of violating mass limitations as a result of wet-weather flows is actually significant and cannot be adequately addressed by accounting for effluent variability.

EPA requests comment on the approach to the development of mass loading rate limits to account for wet-weather effluent variability supported by the proposed Guidance and also solicits information on the effect of wet-weather pollutant contributions on the ability of permittees to comply with mass loading limitations. EPA also requests comment on the alternative identified and any other methods to appropriately account for wet-weather induced effluent variability in the development of WQBELs. Finally, EPA invites comments regarding whether it may be appropriate to only require monthly average mass loading WQBELs, as discussed above in conjunction with procedure 7.A of appendix F, as a mechanism to address wet-weather effluent variability.

H. WQBELs Below the Level of Quantification

Many Great Lakes Water Quality Initiative (GLWQI) pollutants cause unacceptable toxic effects in amounts lower than can be reliably measured by the most sensitive current analytical techniques. Accordingly, the calculated water quality-based effluent limitations (WQBEL) for those pollutants are often below a level that is analytically quantifiable. When the WQBEL is calculated to be lower than a level that can be quantified, it is difficult to determine whether or not the facility is complying with the WQBEL. In these circumstances special techniques may be necessary to assess and assure compliance.

1. Existing National Guidance

NPDES regulations do not require specific procedures when WQBELs are less than quantification. However, several EPA guidance documents have addressed this issue. First, EPA's "Final Guidance on Section 304(l) Listing and Permitting of Pulp and Paper Mills" was released on March 15, 1989 (March 15, 1989 Guidance), which is available in the administrative record for this rulemaking. This document recommends that where WQBELs are less than the detection level for the specified analytical method, the WQBEL should be included in the permit and the quantification level of the analytical method should be the threshold for compliance determinations. This same issue was discussed in EPA's "Strategy for the Regulation of Discharges of PHDDs and PHDFs from Pulp and Paper Mills to Waters of the United States," dated May 21, 1990 ("May 21, 1990 Strategy"), which is available in the administrative record for this rulemaking. The May 21, 1990 Strategy modified the March 15, 1989 Guidance by recommending that the permit writer specify the minimum level (ML) as the compliance evaluation level in permits that limit dioxin.

Finally, in March 1991, EPA published the Technical Support Document for Water Quality-based Toxics Control ("TSD"), which further expanded guidance on this subject. This document is available in the administrative record for this rulemaking. Copies are also available upon written request from the address listed at the beginning of this preamble. The TSD recommends applying the concepts contained in the May 21, 1990 Strategy to all pollutants.

NPDES regulations do specify how samples are averaged to obtain a monthly or weekly discharge limit. According to 40 CFR 122.2, average monthly (weekly) discharge limit means the highest allowable average of daily discharges over a calendar month (week), calculated as the sum of all daily discharges measured during a calendar month (week) divided by the number of daily discharges measured during that month (week). All samples taken must be included in these averages.

2. Great Lakes Guidance

The Great Lakes proposal establishes procedures for addressing: Expression of a WQBEL below a level of quantification in a permit; the appropriate compliance evaluation level (CEL); and permit conditions to be included to ensure compliance when the WQBEL is below a level that can be analytically quantified. This procedure is specified in procedure 8 of appendix F of part 132 of this proposed Guidance.

The Great Lakes Guidance requires that the actual, calculated WQBEL be expressed in each permit. Even though a WQBEL cannot be measured analytically, it must be specified. In addition to the exact WQBEL, the permit must specify the analytical method to be used to analyze the monitoring samples; the CEL; and the measurement frequency. The analytical methods used to analyze wastewater samples must be ones specified in or approved as an Alternate Testing Procedure under 40 CFR part 136. This portion of the Great Lakes Guidance closely follows the guidance of section 5.7.3 of the TSD.

There are many possible ways of defining a CEL. Some examples in current use are: ML, method detection limit (MDL), and practical quantification level (PQL). The Great Lakes Guidance follows the TSD recommendation in that the proposed CEL for the purposes of this procedure is the ML. The CEL is defined in 40 CFR 132.2 of the proposed Guidance as the ML. The ML is defined in 40 CFR part 136 as the level at which the analytical system gives recognizable spectra and acceptable calibration points. An ML is back calculated from method-specific weights and injection volumes. The use of MLs in evaluating acceptable quantification has been used by EPA in the development of the 1624 and 1625 organic analytical methods (40 CFR part 136), and the 1613 analytical method as proposed in 56 FR 5090. In addition, EPA is in the process of developing additional MLs for the other analytical methodologies.

When MLs are not available for a pollutant, the permitting authority must still specify a CEL in the permit. The

permitting authority has the discretion to select the CEL in these instances. EPA expects that the permitting authority will select a CEL that reflects the similar performance of the ML, that is, the CEL defines the lower bound of quantification of a chemical analytical method.

There are several ways that permitting authorities may specify the CEL in the absence of a ML. One way is to use the MDL specified in 40 CFR part 136. The MDL is the minimum concentration of a substance that can be measured and reported with 99 percent confidence that the analyte concentration is greater than zero and is determined from the analysis of a sample in a given matrix containing the analyte.

Another possibility is the minimum quantification level (MQL). MQLs have been developed as an interim measure in the absence of strictly defined MLs. An MQL is defined, similar to the ML, as the lowest concentration at which a particular substance can be quantitatively measured. MQLs for priority pollutants are based upon a literature search of existing information. The primary source selected was the Contract Required Quantitation Levels (CRQLs) and Contract Required Detection Levels (CRDLs) which were developed under the Contract Laboratory Program administered under CERCLA. When CRQLs were compared with the MLs for similar gas chromatography/mass spectroscopy (GC/MS) methods, the results showed that the levels are within the same order of magnitude. Therefore, defining MQLs as CRQLs or CRDLs appears to be appropriate as an interim measure where MLs have not yet been developed. EPA would like to receive comments on the use of MDLs, MQLs or any other measure of the threshold of quantification as an alternative CEL in the absence of MLs.

Procedure 8.A allows the permittee to demonstrate that a higher CEL is appropriate because of matrix interference. Quantification levels are unique for each selected analytical method. The presence of other pollutants in the effluent may cause interference with the analysis and affect the level at which quantification can be assessed. This matrix interference could raise the level at which one is able to determine that a pollutant is quantifiable.

The proposed Guidance in procedure 8.B specifies that a narrative statement should be included in the permit. This statement must explain that the WQBEL for the pollutant is less than the ML. This statement clarifies to both the permittee and the public that it is not currently possible to analytically measure at those levels with available methods and that other procedures for assessing compliance with the effluent limit will be used.

Procedure 8.C of the proposed Great Lakes Guidance proposes text be included in each permit that defines compliance with the CEL for maximum daily permit limits, average weekly limits, and average monthly limits. Procedure 8.C states that any discharge of a pollutant in amounts greater than or equal to the daily CEL for that pollutant is an exceedance. Procedure 8.C further states that, when a permit contains a weekly or monthly limit, all discharges sampled during such time period be averaged according to methods established by the permitting authority, with the average value compared to the weekly or monthly CEL to determine compliance.

Usually, when assessing compliance with weekly or monthly average permit limits, the limit is compared to an average of samples taken during the relevant time period. The permittee is required to supply the minimum required number of samples, and must supply data for additional samples if taken from the appropriate period of time. In some cases, the permit may require only one sample to assess compliance. If one sample is required and supplied, then it represents the average concentration of that pollutant for the entire period of interest.

When the WQBEL is below the CEL, and the effluent data set includes both quantifiable and non-quantifiable samples, the compliance determination is not simple. In this situation, some method must be developed for "averaging" these non-quantifiable values to assess compliance with weekly or monthly average limits. Current EPA Guidance does not specifically address this issue, and today's proposed Procedure allows permitting authorities to specify their own methods for "averaging" values in this situation. EPA invites comment on whether the proposed Guidance should require Great Lakes States and Tribes to adopt uniform methods for averaging quantifiable and non-quantifiable values in this situation and, if so, what such methods should be.

When a WQBEL is below the ML, one cannot make a definitive statement as to whether or not the concentration of the pollutant in the effluent is above or below the WQBEL. Because of this constraint, other requirements are necessary in order to increase the likelihood that the concentration of the pollutant in the effluent is as close to meeting the WQBEL as possible.

Procedure 8.D of the proposed Great Lakes Guidance requires that a pollutant minimization program (PMP) be specified in the permit in this instance. This program would require a facility to develop a pollutant minimization program to reduce all quantifiable levels of the pollutant in all internal or indirect wastewater streams contributing to the permittee's wastewater collection system to maintain the effluent at or below the WQBEL. A PMP shall include, but not be limited to the following: Annual review and semi-annual monitoring of sources of the pollutant, quarterly monitoring of the pollutant in the influent to the treatment system submittal of a control strategy for reducing loading of the pollutants of concern to the treatment system, reporting of actions which are consistent with the control strategy as the sources of the pollutants are discovered, and annual status reporting of activities and accomplishments. EPA invites specific comments regarding whether the conditions of the PMP are appropriate, including whether the frequency for monitoring of the sources of the pollutant (procedure 8.D.1) and the influent (procedure 8.D.2.) are appropriate.

EPA expects the PMP to recognize that there are practical constraints on treatment capabilities. Therefore, EPA does not view the PMP as a zero discharge requirement. Instead, it is viewed as a means to ensure that WQBELs are achieved. The effects of the PMP may be to reduce all levels of the substances in the internal streams to non-detectable levels, but this is not equivalent to a zero discharge requirement. A PMP-type requirement is consistent with the Guidance found in section 5.7.3 of the TSD and in the May 21, 1990 Strategy.

A permittee may consider cost-effectiveness in developing a pollutant minimization program. In considering alternative elements of a pollution minimization program, the permittee may choose to consider the cost-effectiveness of each element. EPA solicits comments on whether the final Guidance should allow a facility to consider cost-effectiveness in developing a pollutant minimization program, and if so, what data the facility should consider in developing the program.

Procedure 8.E specifies that if all samples of the effluent are below the CEL for the maximum daily limits, all required averages are below the CEL for the average weekly and monthly limits, and the conditions of the PMP are met, then the permittee will be deemed in

compliance with the permit. If one of the conditions of the PMP is not met, the permittee is in violation of the permit conditions. If an effluent sample is above the CEL for the maximum daily limit and the average of samples are above the CEL for weekly and monthly average limits, then the conditions of procedure 8.C are invoked.

Special requirements are specified in procedure 8.F of the Implementation Procedures for the cases where BCCs are limited below the quantification level. The special requirements generate additional information with which to use in judging whether or not the discharge is contributing enough of a pollutant to cause bioaccumulation of the pollutant in fish tissue. The additional provisions require the permittee to determine if the pollutant from the effluent is bioconcentrating or bioaccumulating in fish tissue. This condition is also consistent with the section 5.7.3 of the TSD and May 21, 1990 Strategy. Approaches to determine whether a pollutant is bioconcentrating or bioaccumulating are specified in the proposed Great Lakes Guidance. EPA believes that there are many acceptable approaches to performing fish monitoring or effluent bioconcentration studies. Examples of acceptable methods are: "U.S. EPA Interim Methods for the Sampling and Analysis of Priority Pollutants in Sediments and Fish Tissue" (U.S. EPA, 1982), and "Draft Assessment and Control of Bioconcentratable Contaminants in Surface Water" (U.S. EPA, March 1991), which are available in the administrative record for this proceeding. The regulatory authority may require that other approaches be used. If the results of the studies show that the effluent is bioconcentrating or bioaccumulating at unacceptable levels, the control strategy, as part of the PMP, must be reviewed and modified appropriately.

The proposed Great Lakes Guidance provides two approaches for determining unacceptable tissue levels. One approach is to estimate concentrations of a pollutant in receiving waters based upon the levels of the pollutant in the fish tissues calculated using the criteria equations and assumed inputs. If this concentration is above the water quality standards, then ways to modify the control strategy are warranted and necessary. A complementary approach is to compare the level of the pollutant in the monitored fish tissue to the level used to develop the water quality criteria for that pollutant. In both cases, the variability of the bioconcentration test and the calculated dilution of the effluent flow in the receiving water must be considered. EPA welcomes comments on these and differing approaches to defining unacceptable tissue levels and the extent to which "unacceptable tissue levels" should be defined in the text of the procedure.

In addition, the permitting authority may impose other conditions, as provided in procedure 8.H, upon permittees on a case-by-case basis to require: Derivation and/or use of new analytical equipment and/or methods; use of internal waste stream monitoring and mass balance modeling techniques; and use of any other innovative monitoring techniques and results with which to assess compliance with the WQBEL. This section acknowledges the authority of a State under section 510 of the CWA to require more stringent provisions.

3. State and Tribal Adoption Requirements

In order to achieve consistent application of this procedure, the Great Lakes State or Tribe must adopt a procedure that requires: The actual WQBEL derived from the WQS to be imposed in the effluent limitations' table of the permit; the minimum level as the CEL of preference, when available; PMPs to be specified in all permits so that internal sources of the pollutant are being reduced; when the WQBEL is for a BCC, studies to demonstrate whether bioaccumulation or bioconcentration is occurring in fish tissue due to the discharge be submitted, and the results used to modify the PMP, as necessary; and one quantified sample of the pollutant (at or above the CEL) to be considered as an exceedance of the maximum daily limit for that reporting period, and any average above the CEL to be considered as an exceedance of the average limit for that reporting period. The text does not have to be adopted verbatim. However, the permitting authority must show that the above conditions are met.

4. Options Considered

During the Great Lakes Water Quality Initiative process, it was suggested that numerous violations of the WQBEL will occur although actual effluent concentrations may be below the CEL, due to analytical uncertainty surrounding measurements at the CEL. Suggestions were made that other measurement levels, like the MDL or the PQL, would be more appropriate. EPA does not believe that the MDL or PQL would be more appropriate, because: the MDL is not a measure of quantification, and the PQL (which is typically set as a multiple 5 or 10 times the MDL) is not as precise as the ML. EPA invites specific comments if whether other levels would provide a more valid determination of the ability of an analytical method to quantify a pollutant concentration and the published scientific data supporting such levels.

Alternate text was discussed by the Initiative Committees during development of this proposed provision. This text was "Include permit language clarifying that any discharge of the pollutant at or above the detection level is an exceedance requiring further action." This text incorporates two concepts:

a. Averaging effluent samples for a particular reporting period would not be allowed; and

b. Permitting authorities would have the authority to require further action to confirm exceedances of WQBELs. The following text will discuss the Technical Work Group's reasons and other options considered.

The Initiative Committees considered many approaches for assessing values of pollutant measurements below the quantification level. The original Technical Work Group proposal of prohibiting the averaging of effluent samples was chosen as a simple, conservative approach to assessing compliance. As mentioned previously, when a WQBEL is below a detection or quantification level, and the effluent data set includes both quantifiable and non-quantifiable samples, the compliance determination is not simple. The Technical Work Group believed that when a pollutant is detected or quantified in compliance monitoring, then it is known that the pollutant is present in the discharge at levels above the magnitude of the WQBEL. Limited agreement was reached on appropriate means for averaging detected/quantified values with non-detected/non-quantified values.

EPA did not believe that the conservative approach would necessarily be appropriate in all cases, and therefore revised paragraph C of procedure 8 of appendix F as it is published today. Procedure 8.C states that an exceedance of an average limits occurs with respect to a reporting period when the average of a pollutant is above the CEL during that averaging period. The specific means for calculating the average is left to the discretion of the permitting authority.

Several other approaches for assessing values of pollutant measurements below the quantification level were discussed during the Initiative Committees' Work Group meetings and during the drafting of this proposal package. An alternative

approach would be to specify the means for averaging by assigning a value somewhere in the range from zero to the CEL, to the non-quantified samples. A value which assigns an equal amount of risk to the environment and to the discharger is 50 percent of the CEL or the WQBEL, whichever is less. Another approach would be to assign a zero value to all samples below the minimum value, average all of the samples and then compare the result to the WQBEL (even if less than the minimum level). If this approach was selected in the final Guidance, this would require changing the definition of the CEL to equal the WQBEL for both weekly and monthly average effluent limitation. EPA invites comments on these alternative approaches, any combination of approaches, or other approaches to address this issue.

Additional methods for evaluating compliance with mixed data sets of quantified and non-quantified samples are as follows: First, compliance could be assessed by calculating the percentage of quantified samples from the total number of samples, and declaring noncompliance when the percentage of quantified samples is equal to or greater than 50 percent. Another option would be to substitute the WQBEL value for the values which are below the CEL, average all values, and then compare the results to the CEL. If the results are below the CEL, then compliance is declared. If the results are at or above the CEL, then noncompliance is declared. Neither of these approaches were considered by the Technical Work Group, however. EPA believes that these proposals bear some merit and welcomes comments on these and other methods for averaging effluent samples or for accounting for non-quantified samples in determining compliance with effluent limits which are below the level of quantification.

The second concept of the Initiative Committees' version of paragraph C of procedure 8 was addressed because the Committees believed that this text would reduce the effects of potential analytical uncertainty at the detection level. Comments received during the drafting process expressed that when the concentration is close to the DL, the uncertainty regarding the assessment of detection and/or quantification appears to be higher. Chemists typically use some degree of judgment in assessing the amount of a pollutant during the process of analysis. Judgment is used to quantify the amount of a pollutant that is present in a sample, no matter the definition of the detection level. This judgment may, in some cases, result in false positives, i.e., the analysis indicating the presence of a pollutant when the pollutant actually is not present.

The Initiative Committees believed that for analytical results close to the detection level, since there may be uncertainty regarding its validity, the regulatory authority should be allowed to reserve judgement regarding the compliance status of that sample. Permit authority would require further action, for example, increased monitoring of the pollutant for an extended period of time, of the permittee before a final compliance judgement would be made. It was envisioned that once the additional monitoring work was provided or other appropriate actions were completed, an assessment of whether the original point violated the limit would be made by the regulatory authority. EPA did not include this text in proposed procedure 8 of appendix F because EPA maintains that any exceedance of a permit limit including a WQBEL is a violation as defined by section 309 of the CWA. Of course, dischargers always have the opportunity to demonstrate that any measurement is inaccurate or invalid. In addition, because the CEL of preference is the ML, EPA believes that the analytical uncertainty of false detects is less of a concern than if a true detection level were used as the CEL. EPA, however, welcomes comments on all aspects of this issue, including the appropriateness of the original text prepared by the Initiative Committees.

I. Compliance Schedules

A compliance schedule in this context refers to an enforceable sequence of interim requirements leading to ultimate compliance with the requirements of the Clean Water Act. Procedure 9 of the implementation procedures allows schedules for compliance in permits with WQBELs in specified circumstances. However, the permitting authority has discretion not to include compliance schedule provisions.

The circumstances under which a compliance schedule may be provided depend on whether a new discharger, an increasing discharger, or an existing discharger is involved. For purposes of procedure 9, a "new discharger" is defined as any facility which commences discharging on or after the effective date of this regulation. An "increasing discharger" is defined as an existing discharger which on or after the effective date of this regulation has an increase in flow, concentration or loading from that which was previously specified in its permit. An "existing discharger" is defined as any facility which commenced discharging prior to the effective date of this regulation, provided it is not an increasing discharger.

Schedules of compliance are not available for new or increasing dischargers. Procedure 9.A provides that when a permit is issued, reissued, or modified to contain an effluent limitation derived from Tier I criteria, Tier II values, whole effluent toxicity criteria, or narrative criteria for a new or increasing discharger, the permittee shall comply with the new effluent limitations upon the commencement of the new or increased discharge.

The Initiative Committees believed that schedules of compliance for WQBELs should not be available for new or increased dischargers because their changed operations would occur on or after the effective date of this regulation; and hence after they are on notice of the water quality standards which are required under the Great Lakes Initiative. The Initiative Committees believed that it is reasonable to expect immediate compliance with effluent limits derived from the Tier I and Tier II methodologies in these circumstances as soon as the new or increased discharges commence and that this action would further the goal of reducing discharges to the Great Lakes System as soon as possible.

Procedure 9.B addresses the circumstances under which compliance schedules would be appropriate when new or more restrictive limitations are established in permits for existing dischargers. This section provides that when a permit for an existing discharger is modified or reissued to contain more stringent effluent limitations due to Tier I criteria, Tier II values, whole effluent toxicity criteria, or narrative criteria, the permit may allow a reasonable time, not to exceed the term of the permit or three years, whichever is less, to comply with the new limitations. As a matter of practice, EPA has generally supported and allowed a three year maximum on compliance schedules in discussions with States, if this does not extend past the term of the permit. This time frame is also consistent with that provided pursuant to section 304(l) for Individual Control Strategies. During this period, the permittees must comply with either the terms of the previous permit or any more stringent interim limitations and other requirements specified in the schedule of compliance.

If a permit establishes a schedule of compliance which exceeds one year from the date of the permit issuance, the schedule shall set forth interim requirements and the dates for their achievement. Interim requirements may

be construction milestones; they need not necessarily be interim effluent limitations. The time between interim dates for compliance schedules under this provision may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall specify interim dates for the submission of progress reports toward completion of the interim requirements and indicate a projected completion date. Specification of interim compliance dates is currently required in all NPDES permits issued by EPA or authorized States. (40 CFR 122.47, 123.25).

Procedure 9.C provides the discretion for the permitting authority to provide additional flexibility for complying with Tier II limitations in modified or reissued permits for existing dischargers, to accommodate the situation where additional studies may provide the basis for developing a Tier I criteria or modifying a Tier II value. Under these circumstances, the permit may provide up to two years from permit issuance for completion of specified studies (this would occur during the up to three-year period for compliance provided under procedure 9.B). If such studies are completed in a timely fashion, and new criteria or values are developed, the permit may be reopened and modified to reflect the new Tier I criteria or revised Tier II value. As long as the specified studies are completed, whether or not they turn out to justify new criteria or values, the permittee may have a reasonable time, within the remaining term of the permit, to comply with the limit(s) in question. Any additional time which will be granted to a permittee should be appropriate for the activities which the permittee will have to undergo in order to achieve compliance with the revised WQBEL, or, if not revised, the originally established WQBEL. The reasonable time will be determined by a permitting authority on a permit-by-permit basis. For example, if the WQBEL is revised to become less stringent and minor process changes are necessary to achieve compliance, then no additional time may be necessary or additional time may not be more than six months. On the other hand, a facility may need to add on additional treatment involving construction. In this case, two years may be appropriate in order for the facility to achieve compliance. In any case, due to the fact that the permits must be modified in order to incorporate the results of the studies the public would have an opportunity to comment upon the appropriateness of any extension of the compliance schedule as well as the modified WQBEL. In addition, EPA has review authority to ensure that the additional time period is "reasonable" and not based upon a standard practice of granting additional time which equates to the remaining term of the permit. If the studies are not completed in a timely fashion, the permittee must comply under the original not-to-exceed three-year schedule. In addition, the permittee may not presume that a revised WQBEL has been established or additional time for compliance has been provided, until the permitting authority has modified the facility's NPDES permit to reflect these changes.

EPA has long had a practice of considering reasonable schedules of compliance in permits based on newly adopted or revised water quality standards promulgated after July 1, 1977. Recent orders in *In Re Star-Kist Caribe, Inc.*, NPDES Appeal No. 88–5, have emphasized the need for States and Tribes to provide specific authorization for such schedules. In light of the deadline in section 301(b)(1)(C) of the Clean Water Act, which requires that permits assure compliance with applicable water quality standards, these Orders state that schedules of compliance for limitations based on post-July 1, 1977, standards are prohibited unless the standards themselves or State or Tribal implementing regulations expressly authorize such schedules.

Because the implementation procedures proposed today are expected to be adopted by States and Tribes as part of their standards programs or implementation regulations for the Great Lakes System, such adoption will allow the proposed use of schedules of compliance in NPDES permits in those States and Tribal lands. Of course, no State or Tribe is obligated to include a schedule of compliance in a particular permit under the proposed procedures and States or Tribes can be more stringent by not providing for compliance schedules. Because the pollutants in Table 5 are not addressed by procedure 9, any States or Tribes wishing to provide schedules of compliance for limits based on criteria for Table 5 pollutants will need to do so separately.

In addition, facilities being regulated under section 304(l) of the Clean Water Act (CWA) are not exempt from their 304(l) compliance requirements. For example, if facilities are located in one of the Great Lakes States or on Tribal land but were listed on a 304(l) list, their 304(l) compliance requirements cannot be extended by any compliance schedules adopted pursuant to the proposed Great Lakes Water Quality Initiative Guidance.

Another issue which was raised during the development process of procedure 9 is whether the anti-backsliding requirements of section 402(o) of the CWA would apply to limits which have a scheduled date of compliance beyond the effective date of the permit. The anti-backsliding provision of the CWA prohibits reissuing or modifying an NPDES permit to include less stringent effluent limitations unless certain tests are met. The proposed Guidance provides that anti-backsliding restrictions do not apply to revisions to effluent limitations made before the scheduled date of compliance for those limitations. Additional discussion of anti-backsliding requirements is contained in section II.D of today's preamble.

EPA would like to receive comments from the public regarding the three approaches outlined concerning compliance by dischargers with the Tier I criteria and Tier II values presented in Procedure 9.A through C, inclusive, of appendix F. For example, do the timeframes detailed in Procedure 9.B and C provide sufficient time both to comply generally, and, in particular, to adequately complete the necessary studies referred to in these sections? In addition, EPA specifically invites comment on whether it is appropriate to provide for extension of a compliance schedule where a permittee conducts a study as to the appropriateness of a Tier II limitation. EPA has traditionally taken the position that a facility can challenge, study or litigate both technology-based and water quality-based terms and conditions of a permit on its own time, but that these activities do not extend otherwise applicable compliance dates. EPA invites comment on whether the approaches described in Procedure 9.C are appropriate. EPA would also appreciate comment from the public as to whether the time permitted for compliance under the Guidance is appropriate, i.e., if no studies are done, up to three years; or, if the studies are done, whether or not they justify less stringent limits, then up to five years. In addition, another topic for consideration is what factors or procedures should be used by the permitting authority to assess what would be the reasonable amount of any of the compliance period(s) or interim schedule(s). EPA also invites comments on the proposed text precluding compliance schedules for new or increasing dischargers; and the proposed definitions of new, existing, and increasing dischargers applicable to compliance schedules.

IX. Executive Order 12291

A. Introduction and Rationale for Estimating Costs and Benefits for the Great Lakes Water Quality Guidance

Executive Order 12291 requires EPA to prepare a Regulatory Impact Analysis (RIA) for major regulations, which are defined by certain levels of costs and impacts. For example, the Executive Order specifies that a regulation imposing an annual cost and benefit to the economy of $100 million or more is considered major under the terms of the Order. According to the Executive Order, the Regulatory Impact Analysis should contain descriptions of both potential costs and benefits.

Under the Clean Water Act, costs are not directly relevant in establishing water quality criteria. However, if a range of scientifically defensible criteria that are protective of the designated use in question are identified, costs may be considered in selecting a particular criterion within that range. In addition, under EPA's regulations, certain costs can be considered in the context of use attainability analyses, variances, and antidegradation. Moreover, as a matter of good government, EPA likes to be aware of costs and benefits of its proposals. Accordingly, the question of costs and benefits has been an integral part of the deliberations involving the States and EPA in the development of the Great Lakes Water Quality Guidance (GLWQG). In addition to the requirements set forth in Executive Order 12291, the States of Ohio, Michigan and Wisconsin have specifically requested that EPA examine the costs and benefits of the Initiative. Some members of the Public Participation Group also expressed a concern during the Steering Committee meetings that the costs to point sources could be sizeable. Other public comments expressed concern about potential benefits. During the Steering Committee deliberations in November and December 1991, EPA expressly committed to estimate various costs and benefits that could accrue from the proposed GLWQG.

The following discussion describes how EPA has estimated both costs and benefits associated with the proposed Guidance. Aggregate costs are estimated for all direct and indirect dischargers in the Great Lakes System. Benefits and costs are assessed for direct industrial and municipal dischargers at three sites in the System. The results of these case studies are not appropriate to use in evaluating the aggregate benefits and costs of the proposed GLWQG. EPA is requesting comments on the methodologies used to estimate both costs and benefits. Commenters should provide data to support their comments. EPA will evaluate all comments and supporting data received through the public comment process. As noted above, E.O. 12291 requires EPA to prepare a Regulatory Impact Analysis for proposed and final major rules. The studies described below have been submitted to Office of Management and Budget (OMB) to fulfill this requirement. These cost and benefit studies are summarized below. The documents underlying this summary are available in the administrative record for this rulemaking.

B. Overview of Projected Costs Attributable to the Great Lakes Water Quality Guidance

1. Introduction

EPA acknowledges that some point source dischargers, including cities and towns, will incur costs in complying with the requirements of the GLWQG after the proposed Guidance is promulgated and Great Lakes States and Tribes have adopted it. These requirements, when added to current State or Tribe water quality standards and permitting regulations, could require additional construction of treatment facilities and/or process changes, including pollution prevention and waste minimization programs. The magnitude of these incremental costs would depend on the types of treatment or other pollution control installed, the number and type of pollutants treated, and implementation of such pollutant management programs as pollution prevention, community and facility waste minimization programs, and best management practices in a variety of areas.

Similar sources of costs and the variables affecting costs would also apply to indirect industrial dischargers to the extent that the industrial discharger is a source of pollutants discharged to a Publicly Owned Treatment Works (POTW). In addition, the POTW may incur costs for expansion, operational changes, additional treatment, modified pretreatment programs and increased operator training.

Monitoring programs are another source of potential incremental costs to dischargers and regulatory authorities. Monitoring programs to generate information on the existing quality of water and the types and amounts of pollutants being discharged are potentially affected by the imposition of the proposed GLWQG criteria. The addition of criteria and values for toxic pollutants as a result of States' or Tribes' use of the Tier I and Tier II methodologies of the GLWQG can lead to additional compliance monitoring by facilities and regulatory authorities as well as additional ambient water quality assessment costs. However, this monitoring is not solely triggered by the adoption of GLWQG criteria or methodologies, but is contingent on the States' implementation actions in discharger permits and other control mechanisms. Additionally, it is possible that pollution prevention type measures (source reduction and increased recycling) would enable dischargers to reduce their discharges, eliminate pollutants, and therefore decrease monitoring.

Nonpoint sources of pollutants covered by the proposed Guidance may also incur increased costs to the extent that best management practices need to be modified to comply with the revised water quality standards resulting from the aquatic, human health and wildlife criteria adopted under the proposed Guidance. However, there is no Federal permit program requiring control of nonpoint sources comparable to that for point sources. Some Great Lakes States have developed regulatory programs under State law that will require some nonpoint source dischargers to comply with the numeric criteria and values proposed in the proposed Guidance. As these State Nonpoint Source Management Plans are implemented in the Great Lakes, best management practices will begin to reduce discharges from nonpoint sources within an increasing number of drainage basins and will require application of the antidegradation provisions specified in the final Guidance. These costs are not directly attributable to this proposal.

2. Methodology for Estimating Costs to Point Sources Attributable to the Proposed Great Lakes Water Quality Guidance

EPA decided to focus its initial assessment on categories of industries and municipalities that would be both likely to be affected by the proposed Guidance and serve as the bases for a reasonable extrapolation of costs to the universe of Great Lakes System dischargers. Based on a review of lists that States generated and of permits issued since March 1991, EPA assumed that the largest aggregate impact would most likely be on the major direct dischargers. EPA defines major municipal dischargers as those that serve over 20,000 persons and have flows in excess of 1,000,000 gallons per day; there are 316 major municipal dischargers in the System.

In defining major industrial dischargers, EPA considers several factors, including the amount of toxic pollutants in the discharge as well as volume discharged; there are 272 major industrial dischargers in the Great Lakes System. Thus, the GLWQG could affect a total of 588 major industrial and municipal dischargers.

EPA also distinguishes a second group of dischargers, minor dischargers, that fall outside of these definitions. Minor facilities may discharge contaminated process wastes that could have a significant toxic component, or have other characteristics that would be the focus of the GLWQI. There are 3,207 such minor dischargers located in the Great Lakes basin.

These are all the facilities currently permitted by either EPA or the eight Great Lakes States authorized to administer the National Pollutant Discharge Elimination System (NPDES) program—588 majors and 3,207 minors, for a total of 3,795 permittees.

The subset of facilities used in the cost study was selected primarily from the universe of major facilities to enable EPA to reasonably extrapolate the most significant costs in the Great Lakes basin as a whole. After reviewing a variety of lists of facilities—permits issued since March 1991, those recommended by each State and the lists of major and minor facilities—EPA randomly selected 59 facilities (50 major and nine minor). These facilities represented a limited, but practical, number of dischargers for estimating costs and for extrapolating these costs to estimate total costs for all direct dischargers in the Great Lakes basin. EPA conducted a detailed review of these facilities that it considered representative of all types and sizes of facilities in the Great Lakes basin.

Due to differences in the universe of major and minor dischargers, two separate methodologies were used to select representative major and minor facilities. For major dischargers, all randomly selected facilities were grouped into 10 categories which included nine primary industrial groups and a category for municipalities, also known as Publicly Owned Treatment Works or POTWs. The nine industrial categories are: Mining, Food and Food Products, Pulp and Paper, Inorganic Chemical Manufacturing, Organic Chemical Manufacturing/Petroleum Refining, Metals Manufacturing, Electroplating/Metal Fabrication, Steam Electric Power Plants, and Miscellaneous facilities.

This initial categorization of major facilities was then stratified by flow within each category. While each industrial category was divided into two or three flow strata, these distinctions were tailored to each category. The differing flow distinctions were used to decrease reliance on estimating cost strictly based on flow rates and to decrease the skewing effect on the analysis of greatly varying flow rates between categories. EPA feels that flow distinctions chosen independently for each category represent a natural clustering of the flow rate data that put roughly equal numbers of facilities into each flow stratum. These distinctive flow strata were designed to address the following objectives:

a. Ensure that the strata allows for random selection and costing of at least two sites from each flow strata and category of discharge;

b. Ensure a balance in the number of sites within each flow strata to provide roughly proportional representation in the sample of sites with varying flows;

c. Ensure enough flow divisions so that reported flows differ as little as possible within any single flow strata; and

d. Ensure allocation of more sites to discharger categories with a greater number of facilities to allow more flow strata to be formed within these categories.

These objectives allow for greater precision in estimating cost and allow for more efficient extrapolation of the cost estimates to the entire System. Since POTWs represented the largest category of major dischargers, more POTWs were selected from that group to ensure a more statistically reliable representation.

Further, a number of minor facilities were evaluated even though they are not expected to discharge a large number or quantity of toxic pollutants as compared to major dischargers. Because little or no compliance costs are anticipated by minor dischargers, EPA analyzed a limited number of randomly selected minors to verify that assumption. Furthermore, because EPA has little or no flow data for minor dischargers, it is not possible to adopt a flow-stratified analytical plan similar to that for majors. For each facility under review, the most current, necessary NPDES permit data and background information was collected to: calculate the limits that would be anticipated from current regulatory requirements (if not incorporated into the current permit); and develop additional permit requirements based on the proposed Guidance. EPA gathered information from State and Regional files that included permit applications, permit fact sheets or rationale, inspection reports, discharge monitoring reports, pretreatment reports, short-term waste characterization studies, receiving stream low-flow scenarios and total maximum daily loads/waste load allocation reports, and any other readily available information. In most instances, State permit writers were directly contacted to: verify collected information; assist in the interpretation of previous permit limit calculations; and assist in interpreting water quality standards and implementation procedures adopted in the past two years to comply with section 303(c)(2)(B) of the Clean Water Act. Permit writers and water quality experts from the following organizations were consulted: Minnesota Pollution Control Agency, the New York State Department of Environmental Conservation, the Michigan Department of Natural Resources, the Ohio Environmental Protection Agency, the Wisconsin Department of Natural Resources, the Indiana Department of Environmental Management, the Pennsylvania Department of Environmental Resources, the Indiana United States Geological Survey, the Michigan United States Geological Survey, the Minnesota United States Geological Survey and EPA Regions 2, 3, and 5.

For each facility on the review list, new permit limits and additional permit conditions were developed based on the implementation procedures in the proposed Guidance. The proposed criteria would require some permitted facilities to meet new limits and adopt other permit conditions such as whole effluent toxicity testing and additional monitoring. The limits developed for estimating costs were calculated for those 34 pollutants for which numeric Tier I and Tier II criteria and values have been proposed. For a given facility, only those pollutants that were detected in the discharge, or expected to be present in the discharge but were reported as not detected because less sensitive EPA approved analytical methods were used, were evaluated. The need for whole effluent toxicity limits and monitoring was also evaluated in accordance with this proposal. For each facility, limits were calculated for the outfalls that contain or may contain observed or anticipated loadings for the pollutants of concern.

If the existing effluent limits for some of the permitted facilities selected did not reflect current State water quality standards and implementation policies, these differences needed to be accounted for prior to estimating the incremental difference between the current requirements and the GLWQG-based effluent limits. Therefore, prior to comparing the limits and conditions

that are based on the GLWQG, EPA recalculated the permit limits to reflect the newly-revised State standards and requirements that are based on the adoption of toxic water quality standards under section 303 (c)(2)(B) (referred to here as baseline requirements). This approach should reflect more accurately differences between existing effluent limits based on newly-revised State requirements and procedures required in the Initiative. In other words, for older permits, two sets of permit limits were calculated—a first set of permit limits to reflect the current, but not fully implemented, regulatory baseline requirements for facilities, and a second set of limits to determine what the GLWQG will add to these baseline requirements.

In determining specific requirements imposed by the GLWQG, it was necessary to calculate wasteload allocations for discharges to both the open waters of the Great Lakes and their tributaries. In doing so, EPA assumed that the data necessary to calculate total maximum daily loads (TMDLs) would not be available for specific pollutants on specific receiving waters. Therefore, EPA calculated site-specific wasteload allocations for each discharger using equations set forth in the draft implementation procedures. Due to the general lack of background concentration data for receiving waters, two different Waste Load Allocations (WLAs) were calculated for each facility. The first WLA assumed zero background in the absence of background data (WLA #1). The second WLA assumed a value for background concentrations where no background data existed (WLA #2). The assumed background value was based on the average proportion of the actual measurable background data from seven facilities to the GLWQG criteria and values. The assumed background values were approximately 50 percent of the GLWQG water quality criteria and values.

The proposed implementation procedures do not contain specific procedures for converting WLAs into Water Quality Based Effluent Limits (WQBELs). In this study, the daily maximum WQBEL for a pollutant was set equal to the WLA calculated to protect the acute aquatic life criterion (i.e., the Final Acute Value). Monthly average WQBELs were set equal to the most stringent WLA calculated to protect chronic aquatic life, wildlife, or human health criteria. There were several instances when negative WLAs were calculated for a pollutant. This occurred due to high background concentrations of pollutants reported for a receiving water. Since the implementation procedures do not contain procedures for dealing with negative WLAs, two different sets of WQBELs were calculated for each facility, which resulted in different compliance cost scenarios. In cases where negative WLAs were calculated using WLA #1, the WQBEL was set equal to the background concentration (WQBEL #1); when negative WLAs were calculated using WLA #2, then the WQBEL was set equal to the most stringent water quality criteria (WQBEL #2).

The specific assumptions and protocols used in making these calculations are set forth in the Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance. This document is available in the administrative record for this rulemaking. EPA solicits any comments on the methodologies used to estimate costs, including the underlying assumptions and the supporting data used. Commenters should provide data supporting their comments during the public comment period to enable EPA to conduct a thorough evaluation.

3. Determinations of Costs

The three main cost categories assessed are:

a. Treatment costs associated with installation, modification or expansion of treatment systems;

b. Monitoring costs for facilities for the purpose of tracking the presence of toxic pollutants thought or known to be in a discharge, but at levels too low to justify direct regulation through effluent limits; and,

c. Costs related to facility or system management, such as enhancement of pretreatment programs, special studies, toxicity reduction programs, pollution prevention programs and waste minimization.

If the GLWQG-based effluent limits were more stringent than the existing effluent limits either in current permits or calculated against current regulatory requirements, then EPA developed costs to comply with the more stringent effluent limits on a facility-by-facility basis. In developing these cost estimates several factors were taken into consideration, including:

i. Ability of the existing treatment system and process to treat any or all of the pollutants for which GLWQG limits have been calculated;

ii. Whether or not the incremental amount of a pollutant or pollutants to be evaluated were below treatable levels;

iii. Degree to which influent concentrations of pollutants to be treated are present at levels amenable to existing treatment, or would require additional treatment;

iv. Opportunities available for retrofitting existing treatment systems in terms of add-ons, process enhancements, etc.;

v. Opportunities for source reduction through pretreatment program modifications, pollution prevention, waste minimization and best management practices (of particular importance for municipalities);

vi. Treatment options and costs identified in EPA development documents associated with policy, guidance and effluent guideline regulation development; and,

vii. Costs for additional monitoring, implementation of special conditions such as toxic reduction evaluations and special studies to verify presence of suspected toxicants.

These factors were applied to each of the facilities reviewed. Each review is documented in a facility-specific report that outlines the application of the methodology, including the findings and conclusions. These individual, facility-specific review reports and the report collating the information from all of the reviews are available for review in the administrative record. EPA requests public comment on this methodology, the facility reviews and the tentative conclusions set forth below.

4. Estimated Facility Compliance Costs

a. *Basic Considerations.* Following the identification of pollutants of concern for each facility and the development of water quality-based effluent limits based upon the proposed Guidance criteria and implementation procedures, the final step involved an estimate of costs to the particular facilities reviewed. An engineering analysis for each facility in the sample was conducted to develop potential compliance options. This included a review of existing treatment systems at the facility, and an assessment of the need to add new treatment or supplement existing treatment capabilities. Having defined the control options, the compliance costs to facilities implementing each option were estimated. Compliance costs generally included treatment costs, monitoring and operations and maintenance costs, and a variety of one-time costs of limited durations (e.g., waste minimization audits of production processes).

In performing this analysis, EPA used its own development documents for effluent guidelines and standards, the

Office of Research and Development Risk Reduction Engineering Laboratory's RREL Treatability Database, and other information that was available in State or EPA records. This information enabled EPA to develop estimates for the toxic effluent levels currently achieved at facilities and the levels that could be anticipated to be achieved with alternative treatment systems. If this analysis showed that additional treatment was needed, unit processes were then selected as additional end-of-pipe treatment. EPA generally assumed that additional treatment would be added as end-of-pipe because it did not have such process-specific information such as flows, treatment-in-place, process waste characteristics or recycling capabilities that would allow an assessment of other potentially less expensive alternatives. The estimates most affected by the end-of-pipe assumption would be the size of the treatment units because this assumption had to be based on treatment of the entire flow. Where process-specific information was available, however, EPA attempted to develop estimates for treating separate process waste streams.

In several instances, additional end-of-pipe treatment was not projected for a facility. This was the case where existing treatment facilities could accomplish the required treatment, current permit requirements or construction plans were already in place to provide the additional treatment, or the incremental amounts of pollutants to be removed were minimal. In each of these instances, it is not currently anticipated that there will be appreciable treatment requirements directly attributable to the GLWQG.

b. *POTW Costs.* In the case of municipalities, or POTWs, compliance costs are also a function of their ability to implement additional controls through pretreatment programs they administer. Therefore, in setting cost estimates for these systems, consideration was given to the number and types of industrial users discharging to the collection system, as well as the size of the POTW. If additional pretreatment controls or modifications seemed unlikely to achieve the pollutant reductions, then additional treatment at the POTW was considered the next most likely option.

Capital costs were estimated for facilities where the analysis indicated that additional or enhanced treatment was needed. After identification of the treatment system, these costs were then estimated based on the information from such readily available EPA documents as the Development Document for Effluent Limitations Guidelines and Standards for the Metal Finishing Point Source Category (EPA/440/1–83/091) June 1983; Development Document for Existing Source Pretreatment Standards for the Electroplating Point Source Category (EPA/440/1–79/003) August 1979; and Treatability Manual, Volume IV: Cost Estimating (EPA/600/8–80–042d) July 1980, which are available in the administrative record for this rulemaking.

Effluent guidelines and development documents appropriate to each facility's industrial category were also consulted. However, since the majority of the proposed Guidance pollutants of concern were metals, EPA decided that the metal finishing and electroplating development documents were the most appropriate for use in this study. Once the estimates were made, they were converted into first quarter 1992 dollars using the Engineering News Record Construction Cost Index.

For assessing annual costs associated with operation and maintenance of the facilities, the analysis focused on the costs associated with the addition of supplemental treatment systems. These costs were generally based on the same information and sources as the capital costs, and reconciled using the same Engineering News Record Construction Cost Index.

c. *Monitoring Costs.* Monitoring costs for permitted facilities were also estimated. In those cases where additional parameters and limitations were deemed necessary due to the GLWQG, the monitoring regimes (i.e., sampling frequency) were established consistent with the existing monitoring requirements for other parameters. Monitoring costs were then estimated based upon information generated in the development of the draft NPDES Permit Application Form 2A. This information, based on an evaluation of laboratories for costs of over 60 established analytical methods, provides average costs per method for the more common techniques.

As the discharge of bioaccumulative chemicals of concern (BCCs) are of special concern under the proposed Guidance, this study included monitoring-only costs for Tier I BCCs for all effected facilities regardless of whether Tier I BCCs were detected or expected to be present in a discharge. These monitoring costs were estimated using the same average analytical costs described above for determining compliance with effluent limitations.

Residual management costs were also estimated for industrial and municipal facilities that were projected to install end-of-pipe treatment and generate additional sludge (e.g., chemical precipitation). These disposal costs were estimated for each appropriate facility in the sample and then extrapolated to derive total costs for all facilities discharging to the Great Lakes System.

A number of other costs were also considered depending on the specific circumstances surrounding a particular type of facility. These were generally one time costs related to pollutant minimization studies, bioconcentration studies, whole effluent toxicity testing, pretreatment program revisions, waste minimization audits, and implementing pollution prevention techniques. Generally these costs were included with the capital costs for purposes of calculating annualized costs of compliance.

5. Extrapolation of Total Compliance Costs for Sample to the Great Lakes Community of Point Sources

Four different cost estimates were developed to account for differences between limits based on WLA #1 (zero background absent actual data) and WLA #2 (assumed 50 percent background absent actual data), as well as the potential range of costs associated with implementation of waste and pollutant minimization studies and controls. These scenarios are described below:

Scenario 1: Limits based on WLA #1 and the low end of the estimated range of waste minimization costs for all facilities.

Scenario 2: Limits based on WLA #2, the middle of the estimated range of waste minimization costs for industrial facilities, and POTWs aggressively implement the pretreatment program to promote source control (high-end cost).

Scenario 3: Limits based on WLA #2, the middle of the estimated range of waste minimization costs for industrial facilities, and POTWs install end-of-pipe treatment.

Scenario 4: Limits based on WLA #2, high-end of an estimated range of waste minimization costs, and POTWs install end-of-pipe treatment.

The major difference between Scenario 2 and Scenario 3 is the emphasis on pollution prevention versus end-of-pipe. Assumptions underlying Scenario 2 emphasize pollution prevention through source control. Scenario 3 focuses on end-of-pipe treatment, especially at POTWs. EPA believes that facilities will most likely follow the pollution prevention approach to meet the requirements—Scenario 2 will be the most likely scenario of compliance. This approach is also consistent with EPA's desire to

encourage pollution prevention as well as the general preference of facilities to reduce wastes first before considering treatment.

To develop a single cost estimate for each facility for each scenario described above, the three cost categories mentioned above were combined into a single annualized cost, which reflects the annual economic costs associated with recurring activities, repaying capital expenses, and special studies. Annualized costs were calculated by assuming that all capital costs and special study costs would be paid by borrowing money at an interest rate of seven percent and paying it back over a 10-year period. Annual costs of monitoring, operation and maintenance were added directly.

Given a single estimate of the annualized cost for each facility, the procedure for extrapolating costs from the sample to the entire population is pre-determined by the stratified random sampling procedure used to select the subset of facilities examined in detail. Using the single annualized cost figure for each plant, an estimate of the cost for each category/stratum was calculated by averaging the values for individual (sample) plants, and then multiplying by the total (population) number of plants in that category/stratum. The cost estimate for the category is calculated simply by summing over the strata in the category. The cost estimate for the entire universe of facilities is simply the sum across categories. This procedure is followed to estimate costs for each scenario.

EPA has identified an estimated 3,500 indirect industrial dischargers that discharge to POTWs in the Great Lakes System and has developed preliminary estimates of compliance costs for them. These preliminary cost estimates are based on the assumption that indirect dischargers affected by the GLWQG would incur the average cost that same type of direct industrial dischargers would incur under cost Scenario 2. In addition, EPA assumed that costs to categorical industrial users would be higher than the costs to non-categorical significant industrial users. The following four scenarios for indirect dischargers are consistent with the four cost scenarios developed for direct dischargers.

Scenario 1: Assumes that 10 percent of all indirect dischargers in the Great Lakes basin would install treatment controls.

Scenario 2: Assumes that 30 percent of all indirect dischargers in the Great Lakes basin would install additional controls.

Scenario 3: Assumes that 20 percent of all indirect dischargers would install additional controls.

Scenario 4: Assumes that 20 percent of all indirect dischargers would install additional controls.

The estimated percent of indirect dischargers affected by the Initiative was based on an assessment of conditions involving industrial users and their toxic dischargers to a moderately large POTW in the Great Lakes basin.

C. Limitations of the Analysis

1. Limitations in Scope

This analysis addresses costs to point source dischargers and indirect dischargers only. EPA did not attempt to identify the least costly means of controlling a particular pollutant or to estimate costs to nonpoint sources. EPA also did not attempt to estimate the costs associated with other aspects of the GLWQG, such possible future Tier I numeric criteria and use of Tier II values in individual permits, nor does it quantify the incremental costs to States of implementing the proposed Guidance. Alternatively, the study does not account for potential cost savings from less stringent limits that could be granted through the variance provisions. It also does not attempt to estimate cost reductions to direct and indirect industrial and municipal dischargers that are able to allocate part of the burden of pollutant reduction to diffuse sources under State nonpoint source regulations.

2. Impact of Technical Assumptions

Based on the limited resources and data available for this analysis, certain simplifying assumptions were made that could impact estimates of compliance costs. Several of these assumptions and their potential impact on the compliance costs are summarized below.

a. Due to the lack of effluent data, process descriptions, etc., in some of the permit files, as well as the constrained analytical detection capabilities reported by some facilities, it was unclear if some of the pollutants of interest were actually in the effluent at detectable levels. If a facilities' maximum observed values were at or below detection levels, but the detection limit was higher than what is achievable using the most sensitive EPA-approved analytical methods, then for purposes of determining the need for WQBELs, the value of the highest detection limit was used as the maximum effluent concentration. This would tend to overestimate the need to control toxic discharges, and potentially overestimate costs.

b. In the absence of any receiving water critical low flow values, zero flow was assumed (i.e., effluent dominated flow). This most likely results in more stringent WQBELs, and tends to overestimate costs. Additionally, for many facilities the 30Q5 and harmonic mean flows were estimated from the 7Q10 low flow. Use of the actual 30Q5 and harmonic mean could result in either less or more stringent limitations.

c. The most common program component considered for this evaluation for POTWs is development of local limits for the pollutant(s) for which WQBELs were established. Estimation of local limit development costs tend to overestimate compliance costs, as the existing General Pretreatment Program regulations (40 CFR part 403) already require pretreatment POTWs to evaluate the need for new or revised local limits at least every five years.

D. Findings

1. General Observations

a. The proposed Great Lakes water quality criteria and values and implementation procedures did not always result in more stringent effluent limitations for a particular pollutant, as compared to existing permit limitations and conditions or those limitations that would be imposed as a result of current regulatory requirements. This was particularly true for the metals and phenol for which either technology-based and/or water quality-based limitations were commonly found in permits.

b. Some States appear to have implemented controls more aggressively. Therefore, permittees in these States will incur proportionally less compliance costs to comply with the GLWQG.

c. Most of the data contained in permit files (e.g., the permit application) and in PCS was not reported using analytical methods sensitive enough to accurately assess the true impact of the GLWQG. This analysis tended to err on the conservative side, as limits were derived for pollutants that were reported as below less stringent detection levels. Permit writers could require further analyses using more stringent analytical methods to determine whether a pollutant is indeed present.

d. Where GLWQG-based limitations were found to be more stringent than the existing permit limitations, the incremental difference was typically relatively small. Further, in the absence

of an existing permit limitation, the incremental difference between the GLWQG-based limitations and reported concentrations was also found to be relatively small. Generally, on a concentration basis, the incremental difference was found to be less than one part per million (or one milligram per liter).

2. Specific Findings

a. Of the 3,795 direct discharging facilities in the Great Lakes System, about 85 percent of these facilities are minor dischargers. POTWs account for more-than-half (54 percent) of all major dischargers.

b. Over 23 billion gallons per day (total daily average) of wastewater is discharged by major dischargers into the Great Lakes System. The steam electric category alone accounts for over 70 percent of the total daily average flow discharged to the Great Lakes System. Over 40 percent of all direct dischargers are located in Michigan; over 20 percent are located in Ohio.

c. The total annualized compliance costs of implementing the GLWQG to direct and indirect dischargers is estimated to be between $80 million under Scenario 1 and $505 million under Scenario 4 (See Table IX–1). Major increases in costs between Scenario 1 and Scenario 2 are attributed to direct industrial and municipal majors and to indirect dischargers as POTWs implement aggressive source/pretreatment programs. Under Scenario 3, costs to major municipal facilities more than double from Scenario 2 costs as they are projected to install end-of-pipe treatment systems. These additional treatment systems at POTWs will substantially increase the residual management costs—from about $5 million under Scenario 2 to over $200 million under Scenario 3. Costs to indirect dischargers decline under Scenario 3 because POTWs are installing end-of-pipe treatment rather than aggressively implementing the pretreatment program. As a result, a smaller number of indirect dischargers are expected to incur costs.

TABLE IX–1—SUMMARY OF ANNUALIZED COSTS

[First quarter 1992 $, millions]

Cost categories	Scenarios			
	1	2	3	4
Major direct dischargers—Industrial	37.4	61.1	61.5	88.5
Major direct dischargers—Municipal	5.1	41.2	48.9	53.5
Minor direct dischargers	10.5	10.5	10.5	10.5
Indirect dischargers	26.5	79.5	53.0	53.0
Total costs	79.5	192.3	173.9	205.5

Source: Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance.

EPA considers Scenario 2 to be the most likely scenario of the four described above and estimates the annualized compliance cost to be about $192 million. Indirect and direct major industrial dischargers account for 41 percent and 32 percent, respectively, of these costs. Major POTWs account for the largest proportion of total annualized costs borne by any of the category of dischargers; the mining category is estimated to incur the lowest proportion of costs for the universe of industrial categories.

d. Major industrial and municipal facilities would bear about 53 percent of the total annualized costs under Scenario 2 of the GLWQG. Indirect dischargers account for about 41 percent of the annualized costs. Minor industrial and municipal dischargers account for the remaining 6 percent of the total annualized costs. Among the majors, three categories account for the majority (79 percent) of the costs: POTWs (37 percent), organic chemicals/refining (27 percent) and pulp and paper (15 percent).

e. Average plant costs range from about $2,800 to $1,080,000. The three highest average cost categories are organic chemical/refining ($1,080,000), pulp and paper ($305,000), and miscellaneous ($211,400). Although major POTWs make up a large portion of the total cost, the average cost per plant is not among the highest at $130,400.

About 3,200 minor dischargers or small facilities incur an estimated $10.5 million in annualized costs for special monitoring studies. At 5 percent of the total annualized costs, this translates into less than $3,300 per facility.

f. Annualized capital costs account for about 7 percent of the total annual cost for majors, but none of the costs for minors, which are not expected to require investment in treatment technology.

g. Waste/pollutant minimization studies and implementation of appropriate controls/techniques are a very significant portion of the total expected cost of the proposed Guidance. The total annualized costs of such studies make up about 54 percent of the costs for direct dischargers under Scenario 2.

h. The annual cost of monitoring, operating and maintaining equipment, etc., makes up about 36 percent of the estimated annual costs for direct dischargers. Special monitoring studies account for about 4 percent.

E. Provisions in the Proposed Guidance Available for Use at States' Discretion To Mitigate Compliance Costs

The GLWQG includes several provisions that States can use under specified circumstances to allow dischargers to lower their cost of compliance. EPA has not projected the use of these variances in estimating costs. These are summarized below and discussed in more detail in their respective sections.

1. Additional Time To Collect Data To Derive a Numeric Tier I Criteria or a New Tier II Value

Procedure 9 of appendix F to part 132 (Compliance Schedules) provides for States to grant dischargers time to collect additional toxicity data to derive aquatic life, wildlife, and human health criteria or values. These additional data could be used to develop new effluent limits that may be less stringent and hence potentially less costly to comply with.

2. Variances From Water Quality Standards

Procedure 2 of appendix F to part 132 provides for States to grant WQS variances if a discharger follows these

procedures. Such variances could result in lower compliance costs.

3. Mixing Zones

Procedure 3 of appendix F to part 132 includes provisions regarding mixing zones for point source dischargers. Mixing zones generally allow less stringent effluent limitations.

4. Reasonable Potential To Exceed Water Quality

Procedure 5 of appendix F to part 132 provides procedures for determining whether a discharge of a pollutant has the reasonable potential to cause or contribute to an exceedance of water quality standards and, therefore, must be controlled in the NPDES permit through a WQBEL. Under procedures discussed in appendix F, a permitting authority may allow dischargers additional time to derive numeric Tier I criteria instead of Tier II values for consideration in this determination and thereby reduce the likelihood of a finding of reasonable potential.

5. Designated Use Modification

The GLWQG provides methodologies for deriving human health criteria based upon (1) fish consumption and recreational exposure, and (2) fish consumption, recreational exposure and drinking water consumption. A State must provide protection based upon the second category of human health criteria for water bodies that are used as public water supplies. The second category of human health criteria are generally more stringent than the first. Water bodies may be designated as public water supply. But if that use does not exist, this designation may be removed in accordance with the regulations at 40 CFR 130. If the use is removed, then the first set of criteria would apply to the water body, and would result in less stringent water quality-based effluent limitations for dischargers. These provisions are discussed in more detail in section II.E of the preamble.

6. Site-specific Criteria

Procedure 1 of appendix F to part 132 provides for States to develop site-specific modifications to aquatic life criteria and values. These may result in less stringent criteria or values, and subsequent WQBELs, which may be less costly to comply with.

7. Total Maximum Daily Load (TMDL)/ Waste Load Allocation (WLA)

Procedure 3 of appendix F to part 132 provides two options for TMDL development. These options can be used to provide alternative control measures for dischargers potentially subject to water quality-based controls.

a. The State or Tribe may collect sufficient data to support a smaller margin of safety than would otherwise be possible. This would allow establishment of a larger WLA and corresponding less stringent permit limit.

b. The State or Tribe may also allocate or reallocate the available load among various point and nonpoint sources. Such reallocations could be arranged at the request of two or more sources who may have reached an agreement between themselves regarding a shifting of the pollutant reduction burden. Such reallocation could result in less stringent effluent limits for some dischargers.

8. Compliance Schedules

Procedure 9 of appendix F to part 132, allows changes in schedules of compliance for existing dischargers to comply with new criteria and values. Where limits are based on Tier II values, such schedules may allow time to collect data to revise such values before compliance is required.

EPA has not attempted to project the use of these provisions and, therefore, has not estimated the potential savings resulting from their application. Commenters should address the feasibility of using these and other provisions and estimating potential compliance cost savings attributable to the future usage of these provisions.

F. Sensitivity Analyses

As described in section D.1 above, there were several limitations in the scope of the cost study. In an effort to evaluate the impacts of these study limitations on the total estimated compliance cost, several sensitivity analyses were performed.

1. Tier I BCCs Are Found Bioaccumulating

As is required under the proposed GLWQG implementation procedures, when a water quality-based effluent limitation (WQBEL) for a BCC is below the most sensitive analytical detection level, then a pollutant minimization study and a bioaccumulation study must be performed by the facility. For purposes of the cost study, EPA assumed that each of these studies would be performed only during the first year of the permit term; any future costs related to the assessment and control of Tier I BCCs found to be bioaccumulating at unacceptable levels were not estimated. If this situation occurs, however, the proposed Guidance requires the facility to review and modify the pollutant minimization study originally performed to control the discharge of the BCC.

To address this issue EPA performed several calculations to estimate the potential incremental compliance cost. These calculations were based on the assumption that a facility would incur the same pollutant minimization study cost once more (including the costs associated with monitoring, performing an initial assessment, and identification and implementation of control measures). It should be noted that bioaccumulation studies were required for only 20 of the 59 sample facilities examined in the compliance cost study. Incremental costs were calculated under four different assumptions:

a. Assuming each of the permittees required to perform bioaccumulation studies find pollutants in the waste stream which bioaccumulate;

b. Assuming 50 percent of the permittees required to perform bioaccumulation studies find pollutants in the waste stream which bioaccumulate;

c. Assuming 25 percent of the permittees required to perform bioaccumulation studies find pollutants bioaccumulating; and

d. Assuming 10 percent of the permittees required to perform bioaccumulation studies find pollutants bioaccumulating.

To calculate a total incremental cost, EPA extrapolated to the universe of direct dischargers in the Great Lakes System utilizing the same procedures used to calculate the total compliance cost in the cost study.

Using this procedure, the incremental costs under the most conservative assumption (i.e., assuming 100 percent of the facilities required to perform bioaccumulation studies would require additional controls) range from about $10 million to $52 million under the four cost scenarios. Under the least conservative assumption (i.e., assuming 10 percent of the facilities required to perform bioaccumulation studies would require additional controls) incremental costs range from about $1 million to $5 million under the four cost scenarios.

EPA believes that the most conservative assumption (i.e., 100 percent failure) is unlikely to occur; the most likely incremental cost that would be incurred would be between the costs associated with 50 and 10 percent assumptions. Assuming that 25 percent is considered the most likely failure rate, and if cost scenario 2 is considered the most likely compliance cost estimate for the GLWQG, then the total incremental cost related to failure of

bioaccumulation studies would be about $5.0 million dollars annually.

2. Proposed Antidegradation Requirements

The baseline cost study did not address costs associated with the proposed antidegradation requirements. EPA developed preliminary cost estimates of the proposed GLWQG antidegradation policy upon the regulated community of the Great Lakes System. This preliminary analysis is based on the assumption that of the existing 3,795 permittees that will be affected by the GLWQG, approximately 190 (5 percent) are expected to request an increase in permit limitations during a five-year permit cycle. For purposes of this analysis, it is also assumed that certain new facilities will propose to initiate direct discharge and request to lower the water quality. Therefore, an additional 3 percent of the existing minor facilities (3 percent of 3,207, or 96 facilities) and 1 percent of the existing major facilities (1 percent of 588, or 6 facilities) were assumed to represent new dischargers that choose to prepare antidegradation demonstrations, again, during a five year permit cycle. In summary, a total of 8 percent (for minor facilities) and 6 percent (for major facilities) of the total number of facilities in each category and flow strata were assumed for this analysis.

Based on the above assumptions for the number of affected facilities and the results from the cost study, preliminary cost estimates for demonstrating the need for antidegradation were developed. To perform the preliminary analysis, the cost of implementing the results of each of the steps required for an antidegradation demonstration were developed separately (i.e., Step 1—pollution prevention, Step 2—alternative or enhanced treatment, Step 3—social/economic analysis).

a. *Step 1—Pollution Prevention.* The first step a facility must undertake to support a determination for the need for degradation or a justification for the need to lower water quality is to show that implementing pollution prevention measures will not result in compliance with the existing effluent limits. The costs for assessing and implementing waste minimization/pollution prevention measures were derived from estimates contained in the GLWQG cost study. Each of these costs were then multiplied by 8 percent (for minor facilities) and 6 percent (for major facilities) of the total number of facilities in each category and flow strata and totalled.

Assuming that all facilities performing the Step 1 demonstration conclude that implementation of pollution prevention will result in compliance with their existing effluent limits, the annualized compliance costs could range from about $2.7 million (under cost scenario 1) to $6.7 million (under cost scenario 4).

b. *Step 2—Alternative or Enhanced Treatment.* Assuming that all of the facilities performing a Step 1 analysis demonstrate that pollution prevention measures will not eliminate the need to significantly lower the water quality, then all of the assumed facilities would move on to a Step 2 analysis (assuming there is still a desire by all facilities to pursue significant lowering of the water quality). To assess the costs of alternative or enhanced treatment, three different costs were estimated including the additional costs to modify the existing treatment train at a facility, the costs for additional treatment, and reporting costs. These three cost estimates were totalled and then multiplied by 8 percent (for minor facilities) and 6 percent (for major facilities) of the total number of facilities in each category and totalled.

If all assumed existing and new facilities were required to spend up to 10 percent of average capital, and Operating and maintenance costs more than the treatment required to meet relaxed effluent limits, then these additional annualized costs could range from about $300,000 (under scenario 1) to about $724,000 (under scenarios 3 and 4). It is important to recognize that if these costs are incurred, the antidegradation procedures would not require the entity to go to Step 3 and none of the costs associated with Step 3 would be incurred.

c. *Step 3—Social/Economic Impact.* To estimate costs for Step 3 it was assumed that all facilities performing a Tier 1 and Tier 2 analysis are denied their request to lower the water quality (i.e., the facilities did not adequately justify the case for the social or economic benefits of lowering the water quality associated with the proposed action and therefore the facilities must incur the costs associated with treating effluent to current water quality based effluent limits or loading rates). This scenario is assumed to be conservative as it would be expected that many facilities would adequately show that lowering the water quality would result in social or economic benefit. For analysis of Step 3 costs it was assumed that each facility would incur the following costs to prevent the significant lowering of the water quality: the additional costs to modify the existing treatment train at a facility, the costs for additional treatment, and the costs to perform the social and economic analysis. These three cost estimates were totalled and then multiplied by 8 percent (for minor facilities) and 6 percent (for major facilities) of the total number of facilities in each category and totalled.

Estimated annualized costs for Step 3 range from about $1.5 million (under scenario 1) to $3.6 million (under scenarios 3 and 4). EPA considers these costs to be overstated since some pollutant reduction benefits from implementation of pollution prevention alternatives identified in Step 1 will be realized by facilities.

d. *Summary.* In summary, under the worst case, the proposed GLWQG antidegradation procedures could cost the regulated community in the Great Lakes basin approximately $11 million per year. This estimate should be viewed as an overestimate due to the fact that it is highly unlikely that a facility will incur the total cost for each step in the demonstration process (i.e., there will be some treatment benefit at the completion of steps 1 and 2 of the demonstration process). In addition, some facilities may be allowed to lower the water quality if social and economic impacts are demonstrated, and thus the facilities would not be required to incur all the costs for additional treatment. Assuming that Cost Scenario 2 is the most probable cost scenario, then the more reasonable worst case costs related to the proposed GLWQG antidegradation procedures would be about $7 million dollars.

3. Future Detection of BCCs

Preliminary estimates were derived to reflect the potential incremental costs to direct dischargers to the waters of the Great Lakes System if BCCs for which Tier I criteria are proposed in Tables 1 through 4 of Part 132 are detected from increased monitoring. In accordance with the proposed GLWQI implementation procedures, a facility is required to conduct a pollutant minimization study and a bioconcentration study if a water quality-based effluent limitation (WQBEL) for a Tier I BCC is set below analytical detection levels. Based on these requirements, 20 of the 59 facilities evaluated in the cost study would be required to undertake a pollutant minimization and a bioconcentration study. Since the cost study included costs for all facilities to monitor for Tier I BCCs, an analysis was conducted to determine what the incremental increase in pollutant minimization and bioconcentration study costs might be if Tier I BCCs are detected in the discharge. A simple set

of assumptions was used to estimate the possible incremental pollutant minimization and bioconcentration study costs for the entire population resulting from increased Tier I BCC monitoring. These assumptions include: each facility in the population is expected to detect, at most, one of the 11 Tier I BCCs; and 25 percent of the facilities in the population are expected to detect one Tier I BCC. The costs to perform the pollutant minimization study and the bioconcentration study were estimated using the same procedures and cost assumptions used in the cost study analysis—excluding monitoring costs.

The resulting total incremental annualized costs are estimated to range from $13.4 million (under Cost Scenario 1) to $37.3 million (under Scenario 4). Assuming that Cost Scenario 2 is the most likely scenario, then the estimated incremental cost is $27.8 million annually. It should be noted that the cost contribution by minors account for more than 50 percent of the additional cost. Because minors generally do not have toxics in their discharge, they are not expected to detect any Tier I BCCs in their discharge. Thus, the additional costs are perceived to be overestimates.

4. Elimination of Mixing Zones for BCCs

The proposed GLWQG implementation procedures require that within 10 years after the effective date of the regulation, waste load allocations (WLAs) for BCCs be set to the most stringent water quality criterion or a fraction of the WLA that has been established (i.e., no mixing zones will be allowed). EPA assessed the potential costs resulting from future elimination of mixing zones for BCCs for facilities that were evaluated in the cost study.

To assess this future impact, EPA compared the existing most stringent GLWQG-based WQBEL with the most stringent water quality criterion for the 20 of 59 facilities required to comply with Tier I BCC WQBELs. Presumably, if some or all of these 20 facilities have to comply with a more stringent limitation(s) (i.e., water quality criteria) in 10 years, then they will incur costs beyond what was estimated in the compliance cost study. EPA also presupposed that the results derived from the evaluation of these 20 facilities would be a good general indication on the likely impact on the entire population of dischargers. The results of this comparison are provided below:

a. Fifteen facilities had existing WQBELs for Tier I BCCs that were equal to the most stringent proposed numeric water quality criteria. In addition, both the WQBEL and the water quality criteria were below the most sensitive detection levels by at least one order of magnitude. Thus, these facilities, as evaluated under all of the assumptions in the compliance cost study, would not be expected to incur any additional costs because elimination would not require further reductions.

b. For seven facilities, proposed water quality criteria were more stringent than the WQBELs. These facilities would appear to be candidates for incurring additional compliance costs 10 years from the effective date of the regulation. For facilities listed in this finding, however, the WQBEL was at least one order of magnitude less than currently achievable detection levels (and consequently the water quality criteria was even further below detection levels). While in theory, one can assume that a water quality criterion, by virtue of its being less than the WQBEL, will result in additional costs and/or impacts for facilities, a practical justification appears difficult—unless the detection limit for each Tier I BCC in this category can be lowered by the time compliance with water quality criteria are required (10 years). Thus, because of the inability to predict where the detection limit might lie in 10 years, the prediction of future costs has no basis at this time for facilities in this finding.

c. For two facilities, only one Tier I BCC (endrin) had a detection level that was lower than both the WQBEL and the water quality criteria. In these cases, it was determined that the WQBEL and the water quality criteria were in the range where costs associated with compliance with both requirements can be anticipated. But both of these facilities had existing permit limits for endrin that are more stringent than the calculated WQBEL. Thus, the existing permit limit was compared to the most stringent proposed water quality criteria. In both cases, the permit limit is very close to the proposed water quality criteria implying that any future compliance costs would be minimal. Further, these facilities were already projected to incur costs for the control of other pesticides for which GLWQG-based effluent limits were established. Based on this, EPA believes that future compliance costs for endrin are negligible for both of these facilities.

Also, one of the two facilities had a WQBEL for heptachlor that was greater than the detection level. The most stringent water quality criteria, however, was below the most sensitive detection level by one order of magnitude. For the same reasons discussed for endrin, the cost impact is expected to be minimal.

d. In summary, EPA's conclusions, based on an evaluation of the 20 facilities on the future impact of the elimination of mixing zones are:

i. The current compliance cost estimate appears to have indirectly taken into consideration the impact of end-of-pipe requirements for Tier I BCCs for the majority of facilities in the sample. Generally, the population of dischargers is likely to exhibit the same characteristics. For these facilities, no future impacts are anticipated.

ii. Since changes in analytical detection levels cannot be predicted and/or are unlikely, facilities that have a more stringent water quality criteria than a WQBEL, on a practical basis, are the same as the facilities where the WQBEL and the water quality criteria are the same.

iii. Assuming that no significant changes in analytical detection levels occur over time, only two Tier I BCCs (endrin and heptachlor) are expected to cause additional costs from end-of-pipe requirements for a very small portion of the sample (2 facilities). These costs are expected to not be significant.

5. Prevalence of Tier II BCCs and Potential BCCs

Since the cost study focused only on pollutants with proposed Tier I numeric criteria, the estimated compliance costs reflect only those costs associated with complying with water quality-based effluent limitations (WQBELs) for Tier I BCCs. Acknowledging that there may be future costs associated with regulating additional BCCs and potential BCCs using Tier II values, EPA evaluated how prevalent such Tier II BCCs and potential BCCs were in the discharges of the 59 facilities examined for the cost study. Using the results of this evaluation, some general conclusions were drawn on what the cost impact might be if facilities are required to comply with future Tier II BCC and potential BCC requirements. The two-tiered approach is discussed in more detail in section II.D.

To evaluate Tier II BCCs and potential BCCs, EPA re-examined the files of the 59 sample facilities considered in the compliance cost study. Permit application data and any other data in the permit file were reviewed to determine if any Tier II BCCs and potential BCCs were pervasive in the facilities' effluent. As part of the evaluation EPA also examined each facility's existing permit to determine if any Tier II BCCs and potential BCCs are currently regulated (i.e., limited and/or monitoring requirements). The findings indicate that:

a. A total of 28 out of 50 facilities had monitoring data that ranged from a few (5) to most (27) of the 32 Tier II BCCs. (Nine of the 59 in the sample belong to the two minor categories. None of the minor facilities had analytical data for the Tier II BCCs and potential BCCs. Thus, only the results of facilities in the major categories (50) are reported.) Out of these 28 facilities, only two facilities detected a Tier II BCC. Moreover, these facilities detected only two of the 17 Tier II BCCs. These facilities detected one potential BCC each; and only 2 of the 15 Tier II potential BCCs.

b. Sixteen of the 50 facilities did not provide any monitoring data (the majority of which fall into the major POTW category).

c. Nine of the 50 facilities did not provide any monitoring data but reported that the BCCs were believed absent for some or most of the Tier II BCCs and potential BCCs.

d. The detection levels reported for virtually all Tier II BCCs and potential BCCs were higher than the most sensitive currently achievable detection levels.

e. The concentrations of Tier II BCCs and potential BCCs detected were generally less than current Federal water quality criteria.

f. Twelve of the 50 facilities had monitoring or other permit conditions for several of the Tier II BCCs and potential BCCs.

In summary, if water quality criteria are developed for Tier II BCCs and potential BCCs under the GLWQI and these criteria become permit requirements, the increase in compliance costs for additional treatment and/or control costs is not expected to be significant. This preliminary conclusion is based on the fact that several Tier II BCCs and potential BCCs are already regulated in permits for 12 of the sample facilities, as well as the fact that, based on discharge data reported by sample facilities, Tier II BCCs and potential BCCs were not often detected by the sample facilities in their effluent streams. It should be noted that EPA is aware that a key consideration regarding the available data is that the currently reported detection levels may be masking the presence of some Tier II BCCs and potential BCCs present in lower concentrations. This preliminary conclusion is also underscored by the fact that the presence of a water quality criteria or value for a BCC (or any pollutant) does not explicitly mean that a facility will incur any additional compliance costs. Even if a water quality criterion or value has been developed, it may be highly unlikely that the BCC is actually present (at least for most of the industrial categories), so no compliance costs (other than monitoring) would be borne by the facility.

6. Evaluation of Intake Pollutant Options

The proposed GLWQG implementation procedures at procedure 5.E of appendix F of the preamble provide a proposed mechanism for permitting authorities to consider the presence of intake water pollutants in a facility's discharge when determining the necessity for WQBELs. Procedure 5.E of appendix F would allow the permitting authority to determine that the return of identified intake water pollutants to the same body of water under specified circumstances does not have the reasonable potential to cause or contribute to an exceedance of water quality standards. Based on this determination, the permitting authority would not be required to establish WQBELs for the identified intake water pollutants. This procedure would apply to facilities that return unaltered intake water pollutants to the same body of water without increasing the mass loading rate or concentration of the pollutant at the edge of any available mixing zone, and that do not discharge the intake water pollutants at a time or location that would cause adverse water quality effects to occur that would not have occurred if the pollutants were left in place. EPA compared the cost study assumptions and methodologies to the options presented in the proposed regulation in an attempt to evaluate the associated compliance cost implications.

As previously described in section I.B.2 of this preamble, for the purpose of the cost study, EPA chose to handle pollutants in intake water in several ways in the cost study. First, WQBELs were not calculated for outfalls that contained uncontaminated non-contact cooling water that was withdrawn from the same water body to which it was discharged. This is consistent with the proposed Guidance in procedure 5.E of appendix F where a regulatory authority could determine that there is no reasonable potential to exceed a Tier I criterion or Tier II value if certain conditions are met. EPA believes that most uncontaminated once-through non-contact cooling water would meet these conditions. In addition, to evaluate the costs associated with other options for addressing intake water pollutants where the pollutant concentrations exceed Tier I criteria or Tier II values, the WQBELs were calculated in two different scenarios:

a. WQBEL Scenario #1: WQBELs were set to the intake water column concentration regardless of the source of the intake water.

b. WQBEL Scenario #2: WQBELs were set equal to the most stringent criterion regardless of the source of the intake water.

Because the cost study used an approach that combined provisions of several of the intake credit options presented in this preamble, no direct comparison was possible between the cost study estimates and the total costs related to the proposed options for allowing intake credits. However, the methods used to address instances where the intake water concentrations exceeded Tier I criteria and Tier II values and the resulting compliance cost estimates appear to bracket the total costs of each of the intake credit options, with the exception of the proposed Guidance and alternative Option 1.

Proposed procedure 5.E of appendix F is likely to have its greatest application with cleaner discharges such as once-through non-contact cooling water. For this reason, the rationale discussed above for excluding non-contact cooling water from cost consideration is somewhat consistent with the proposed Guidance. It is possible that some non-cooling water dischargers that were not excluded from the cost evaluation would also meet the conditions necessary for a permitting authority to determine that there is no reasonable potential to exceed a Tier I criterion or Tier II value. The impact of this potential on cost estimate cannot be accurately predicted because the permit file information is insufficient to determine whether each of these facilities meet the five conditions associated with proposed procedure 5.E of appendix F.

Under the remaining alternative options for addressing intake water pollutants, depending on whether the WQBEL is set equal to the receiving water concentration, the water quality criterion (WQC) or at an alternate level, the cost study WQBEL #1 and WQBEL #2 scenarios may or may not be consistent. Generally, estimated costs to comply with the WQBEL #1 scenario may reflect the costs associated with the alternative options that may potentially result in establishment of WQBELs equal to the background or intake pollutant concentration (i.e., portions of Options 2, 3, and 4).

Alternatively, costs to comply with the WQBEL #2 scenario may reflect the costs associated with the alternative options that result in establishment of WQBELs at the lowest water quality

standard or criterion (i.e., Option 4b). The estimated cost to comply with WQBEL #1 scenario is represented by Cost Scenario 1 ($56.7 million per year for direct dischargers). The estimated costs to comply with WQBEL #2 scenario is represented by Cost Scenarios 2, 3, and 4 (ranging from $112.8 million to $452.4 million per year).

Assuming Scenario 2 is the most likely of the costs associated with complying with the WQBEL #2 scenario, then the potential costs associated with the options addressing intake water pollutants generally range from $52.9 million to $112.8 million per year. For a given option, the actual total costs would realistically tend to move toward the lower end of the range because (1) if more pollutant data was available, more situations where the intake water pollutants exceed Tier I criteria and Tier II values may be revealed, resulting in potentially greater application of the proposed Guidance; and (2) the compliance costs for all options except 1 and the proposed Guidance do not include any cost reductions that would result from application of phased TMDLs, variances or specific modifications to criteria. The extent of such cost reductions cannot be estimated because of the site-specific nature of such allowances data limitation.

Alternatively, if existing mechanisms (e.g., variances and phased TMDLs, and site-specific criteria modification) are not utilized by a regulatory authority, the potential compliance.costs may increase.

7. Summary

Sensitivity analyses of major cost study technical assumptions were performed to determine the potential impact on the total estimated compliance cost attributable to the proposed Guidance. Table IX–2 summarizes the results of these analyses.

TABLE IX–2—SUMMARY OF OTHER POTENTIAL COMPLIANCE COSTS NOT ADDRESSED IN THE GLWQG COST STUDY

	Annualized costs (first quarter 1992 $, millions)
Original Cost Study Estimate.	192.3
1. Costs if Tier I BCCs are Found Bioaccumulating.	5.0
2. Costs Related to Proposed Anti-Degradation Requirements.	7.0
3. Costs Related to Future Detection of Tier I BCCs.	27.8
4. Costs Related to Elimination of Mixing Zones for BCCs.	Unknown—Increase expected to not be significant.
5. Costs Related to Prevalence of Tier II BCCs.	Unknown—Increase expected to not be significant.
6. Costs Related to Intake Credit Options.	Unknown—Can result in either cost savings or additional costs.

Note: All costs reflect Cost Scenario 2.
Source: Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance.

Based on the sensitivity analyses performed, and as summarized in Table IX–2 above, an additional $40 million annually in costs may also be attributable to the proposed Guidance. This incremental cost represents about a 21 percent increase above the cost study estimate. If added to the most likely cost study estimate (i.e., Cost Scenario 2), the total compliance costs could reach as high as $232 million annually.

G. Future Analyses

In addition to refining the cost estimates for the RIA that EPA will prepare as part of the final rulemaking, several other analyses will be performed. EPA will assess the economic impact of the estimated costs on both industrial dischargers and municipal facilities, including an assessment of the impacts on small businesses. The results of these analyses will be placed in the record for this rulemaking.

The final EPA analysis will include an economic assessment of various options that are available to implement the final Guidance, the effect of the final Guidance on State implementation policies, especially for facilities that are not discharging to the waters of the Great Lakes System, policy implications of implementing the proposed Guidance in States not part of the Great Lakes System, and the relevant contributions of other sources of pollution to the waters of the Great Lakes System. EPA will also assess the potential for using market-based incentives (e.g., effluent trading between point and nonpoint sources) that can be used to achieve compliance with the requirements of the proposed Guidance.

H. Cost-effectiveness

1. Introduction

Cost-effectiveness values can be used to compare the efficiency of one regulatory option in removing pollutants to another regulatory option. Cost-effectiveness is defined as the incremental (to another option or to a benchmark, such as existing treatment) annualized costs of a pollution control option per incremental pollutant removal (measured in copper-based pounds equivalent). In other words, the cost-effectiveness value represents the unit cost of removing the next pound-equivalent of pollutant.

The cost-effectiveness analysis is a useful tool for evaluating regulatory options for the removal of toxic pollutants. A cost-effectiveness calculation is simply a ratio of the annualized costs of a control option for a group of dischargers to the pollutant loadings removed from surface waters by that option. Three factors are of particular importance in the cost-effectiveness calculations. First, the analysis is based on removals of pounds-equivalent—a term used to describe a pound of a pollutant weighted for its toxicity. Use of pound-equivalent values reflects the fact that some pollutants are more toxic than others and enables removals to be summed across pollutants. Copper is used as the standard pollutant for developing toxic weighting factors. Second, where there are a number of control options being evaluated, the analysis is often done on an incremental basis—using the incremental cost and removals of one control option compared to another option or to existing treatment. Third, cost-effectiveness values are considered high or low only within a given context, such as similar discharge status or for comparison with other industries.

2. Pollutant Loadings Reductions

Pollutant loadings reductions were estimated to indicate the decrease in pollutants discharged due to more stringent GLWQG limits. Baseline loadings were determined in pounds per day by multiplying the permit limit or effluent concentration by the facility's flow rate and a conversion factor. If either the permit limit or effluent concentration for a pollutant was reported as less than a detectable level, the reported detection level was divided in half. Using extrapolation procedures

similar to those used for compliance costs, sample facility baseline loadings were averaged across all facilities in each strata, multiplied by the total number of facilities in each strata, and summed. Total baseline loadings for each pollutant for all direct discharging facilities are shown in Table IX–3 under baseline.

TABLE IX–3.— POLLUTANT LOADING REDUCTIONS

[Lbs/day]

Pollutants	Baseline	Scenario 1 reduction	Scenario 1 percentage change	Scenario 2 reduction	Scenario 2 percentage change
Arsenic	53.56	1.10	2	1.09	2
Benzene	0.00	0.00	0	0.00	0
Cadmium	5,760.89	5,367.95	93	5,622.53	98
Chlordane	1.17	0.43	36	0.80	68
Chlorobenzene	0.00	0.00	0	0.00	0
Chromium III	3.38	0.00	0	0.00	0
Chromium VI	15.33	9.44	62	10.58	69
Copper	78,598.67	75,664.12	96	76,292.93	97
Cyanide, free	77.31	32.84	42	34.93	45
Cyanide, total	0.09	0.00	0	0.00	0
4,4'DDT	0.32	0.00	1.6	0.00	1.6
Dieldrin	0.15	0.10	66	0.10	66
2,4-Dimethylphenol	0.00	0.00	0	0.00	0
2,4-Dinitrophenol	0.00	0.00	0	0.00	0
Endrin	0.00	0.00	0	0.00	0
Heptachlor	0.37	0.11	29	0.21	57
Hexachlorobenzene	1.50	0.17	11	0.17	11
Hexachloroethane	0.00	0.00	0	0.00	0
Lindane	0.00	0.00	0	0.00	0
Mercury	56.58	38.79	68	45.89	81
Methylene Chloride	0.00	0.00	0	0.00	0
Nickel	8,659.86	80.27	1	92.78	1
Parathion	0.00	0.00	0	0.00	0
PCBs	3.16	0.23	7	0.41	13
Pentachlorophenol	6.84	1.09	16	2.02	29
Phenol	0.00	0.00	0	0.00	0
Selenium IV	0.00	0.00	0	0.00	0
Selenium VI	0.00	0.00	0	0.00	0
Selenium, total	911.50	903.51	99	903.77	99
2,3,7,8-TCDD	.00059	.00056	95	.00056	95
Toluene	0.67	0.00	0	0.00	0
Toxaphene	6.40	0.05	1	0.05	1
Trichloroethylene	27.17	26.11	96	26.11	96
Zinc	9,225.14	1,017.05	11	1,048.61	11
Totals	103,410.07	83,143.88	80	84,082.98	81

Note: Numbers may not add due to rounding.
Source: Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance.

Scenario 1 (reflecting WQBEL #1) and Scenario 2 (reflecting WQBEL #2) loading reductions were calculated by finding the difference between the existing permit limits and the GLWQG limit for each pollutant. The resulting difference was converted to pounds per day by multiplying the difference by the facility's flow rate and a conversion factor. Several assumptions were made to calculate the loading reduction for a pollutant:

a. If the difference between the GLWQG water quality-based effluent limitation (WQBEL) and the highest reported concentration was negative, zero reduction was assumed. This situation occurred because there were instances where the reported concentration was below the GLWQG WQBEL.

b. When the highest reported concentration was reported as below a detection level, one-half of this level was used as the baseline concentration.

c. If GLWQG WQBEL was below analytical detection levels, the limitation was set equal to the detection level divided by two for purposes of calculating a difference.

d. It was assumed that facilities are discharging at the level of the existing permit limitation.

Loading reductions were calculated for each direct discharging facility in the sample and then extrapolated to all direct discharging facilities in the Great Lakes System (costs and pounds removed from indirect dischargers are excluded from these calculations). These are also shown in Table IX–3.

As shown in Table IX–3, Scenarios 1 and 2 reduce the loadings of toxic pounds by about 80 percent. In general, metals are reduced by a much higher percent than the organic pollutants.

3. Toxicity-Weighted Loadings Reduction

The pollutant loading reductions from direct dischargers were weighted to compare to national standards using EPA toxic weights (EPA/OST 1988 Cost Effectiveness Criteria and Weights). Toxic weighting factors are derived primarily from chronic freshwater criteria and toxicity values. However,

both human and aquatic criteria are used in cases where a human health criterion has been established for the consumption of fish. Toxic weights along with toxicity-weighted pounds are shown in Table IX–4 as are the reductions associated with Scenarios 1 and 2.

TABLE IX–4.—POUND-EQUIVALENT LOADING REDUCTIONS

[lbs-equivalent/day]

Pollutants	Toxic weights	Baseline pounds equivalent	Scenario 1 reduction pounds equivalent	Scenario 1 percent change	Scenario 2 reduction pounds equivalent	Scenario 2 percent change
Arsenic	32.03	1,715.53	35.08	2	35.08	2
Benzene	0.03	0.00	0.00	0	0.00	0
Cadmium	5.09	29,322.96	27,322.89	93	28,618.68	98
Chlordane	2,468.99	2,880.77	1,053.17	37	1,966.60	68
Chlorobenzene	0.00	0.00	0.00	0	0.00	0
Chromium III	0.02	0.09	0.00	0	0.00	0
Chromium VI	35.50	544.29	335.24	62	375.70	69
Copper	0.46	36,682.00	35,312.45	96	35,605.91	97
Cyanide, free	1.07	83.26	35.37	42	37.61	45
Cyanide, total	1.07	0.10	0.00	0	0.00	0
4,4'DDT	28,933.33	9,336.58	150.34	1.6	150.34	1.6
Dieldrin	10,315.78	1,599.11	1,053.24	66	1,053.24	66
2,4-Dimethylphenol	0.00	0.00	0.00	0	0.00	0
2,4-Dinitrophenol	0.18	0.00	0.00	0	0.00	0
Endrin	2,436.84	0.00	0.00	0	0.00	0
Heptachlor	3,404.71	1,262.56	362.06	29	721.95	57
Hexachlorobenzene	756.80	1,131.97	131.04	11	131.04	11
Hexachloroethane	0.07	0.00	0.00	0	0.00	0
Lindane	76.96	0.00	0.00	0	0.00	0
Mercury	505.02	28,573.71	19,589.40	68	23,174.89	81
Methylene Chloride	0.03	0.00	0.00	1	0.00	0
Nickel	0.09	788.05	7.30	0	8.44	1
Parathion	430.76	0.00	0.00	0	0.00	0
PCBs	7,488.60	23,681.45	1,701.98	7	3,047.29	13
Pentachlorophenol	0.43	2.95	0.47	16	0.87	29
Phenol	0.00	0.00	0.00	0	0.00	0
Selenium IV	0.16	0.00	0.00	0	0.00	0
Selenium VI	0.16	0.00	0.00	0	0.00	0
Selenium, total	0.16	146.12	144.84	99	144.88	99
2,3,7,8-TCDD	40,005,600.00	23,532.48	22,450.43	95	22,450.43	95
Toluene	0.00	0.00	0.00	0	0.00	0
Toxaphene	28,767.12	184,160.89	1,567.12	1	1,567.12	0
Trichloroethylene	0.00	0.26	0.24	96	0.25	96
Zinc	0.05	470.48	51.87	11	53.48	11
Totals		345,915.60	111,304.55	32	119,143.84	34

Note: Numbers may not add due to rounding.
Source: Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance.

The proposed Guidance would reduce the toxicity-weighted pounds, or pounds-equivalent, by about 32 percent under Scenario 1 and by about 34 percent under Scenario 2.

4. Cost-effectiveness

The cost-effectiveness values are calculated by multiplying the pounds-equivalent per day, shown in Table IX–4, with 365 days to derive total annual pounds-equivalent reduced under each scenario. Total annualized costs for direct dischargers in each scenario are then divided by total annual pounds-equivalent for each scenario to estimate the $/lb-eq. for each scenario. The cost-effectiveness of all four cost scenarios ranges from $1.30 per pound-equivalent to $10 40 per pound-equivalent over the baseline; the cost-effectiveness of the most likely scenario is $2.60 per pound-equivalent. The costs for and pounds-equivalent removed from indirect dischargers are not included in these calculations. When compared with the cost-effectiveness of various effluent guidelines, these values are at the low end of the range of $1–$500.

5. Sensitivity Analysis

Two additional analyses were conducted to assess the impact on the cost-effectiveness of assuming that baseline values reported as less than a detectable value equal one-half the reported detection level. The following alternatives for addressing baseline values reported as less than a detection level (in the absence of a permit limit) were evaluated:

a. The reported detection level was used as the baseline concentration.

b. Zero was used as the baseline concentration.

Using the first alternative resulted in about a 22 percent increase in total annual pounds-equivalent removed for Scenario 1 and about a 20 percent increase in total annual pounds-equivalent removed for Scenarios 2–4 when compared to the original analysis. Cost-effectiveness values ranged from $1.07 per pound-equivalent to $8.72 per pound-equivalent.

Using the second alternative resulted in about a 22 percent decrease in total annual pounds-equivalent removed for Scenario 1 and about a 20 percent

reduction in total annual pounds-equivalent removed for Scenarios 2–4 when compared to the original analysis. This assumption yielded cost-effectiveness values ranging from $1.68 per pound-equivalent to $12.87 per pound-equivalent for Scenarios 1–4.

I. Overview of Projected Benefits Attributable to the Great Lakes Water Quality Guidance

1. Introduction

The benefits analysis is intended to provide insight into both the types and potential magnitude of the economic benefits expected to arise as a result of the GLWQG. A qualitative assessment of these benefits is provided in section I.2 below. In addition to the qualitative assessment, more quantitative empirical estimates of the potential magnitude of the benefits from controlling point sources are developed to the extent feasible and then compared to the estimated costs of controlling point sources in the proposed Guidance. This discussion is intended to demonstrate data needed and a methodology suitable for comparing benefits and costs. The methodology used to assess benefits and its results are summarized below. A complete study, Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance, is available in the administrative record for this rulemaking. EPA invites comments and requests that the commenters provide detailed analysis and data to support their conclusions. The appropriate documentation would enable EPA to better evaluate these comments.

2. Qualitative Assessment of Benefits Associated With the Great Lakes Water Quality Guidance

This section provides a qualitative review of the benefits that can be expected from implementation of the proposed Guidance. This qualitative assessment presents a characterization of anticipated benefits based on: (a) The sensitivity and unique attributes of the receiving waters, (b) the nature of the toxic pollutants addressed by the GLWQG and some implications of the proposed Guidance for human health and ecological risk reductions, and (c) an overview of exposed and sensitive populations.

a. *Sensitivity and Unique Attributes of Receiving Waters.* Bioaccumulative chemicals of concern have been identified for special treatment in the GLWQG. EPA believes addressing these pollutants will yield particularly high benefits given the sensitivity and vulnerability of this aquatic ecosystem. Several characteristics of the Great Lakes make them particularly susceptible to relatively nondegradable, lipophilic chemicals, such as some of the contaminants addressed by the Great Lakes Water Quality Guidance. These characteristics include:

i. Long hydraulic retention time. (Less than one percent of the total volume of the Great Lakes drains through the St. Lawrence River on an annual basis. Retention times range from 173 years for Lake Superior to 2.7 years for Lake Erie.)

ii. Low suspended solids concentration.

iii. Low biological productivity.

iv. The presence of self-contained, vulnerable plant and animal populations.

These attributes result in contaminants remaining in the Great Lakes System for long periods of time and bioaccumulating in fish and wildlife at concentrations that are orders of magnitude above those in the water column. Continued or new inputs of toxic pollutants only exacerbate this problem. However, reductions in loadings of pollutants will, over the long term, reduce the rate of bioaccumulation (see sections I.A. and I.D. of this preamble for further discussion).

Because physical and biological processes in the Great Lakes encourage the recycling of toxics, pollutant loadings entering the Great Lakes System may be more likely to impact Great Lakes' wildlife, human and aquatic communities than in other ecosystems. Pollutants like the BCCs identified in the proposed Guidance tend to preferentially sorb to particles in the water column, and are subsequently transported to the bottom sediments in many locations. Because the Great Lakes efficiently cycle carbon and nutrients, higher trophic levels are exposed to many of the chemicals associated with biotic particles and create the risk of these chemicals bioaccumulating up the food chain. Pollutants are also released back to the water column as particulate matter is degraded by bacterial action, posing further risks to the fish and wildlife. Even those particles that do reach the bottom sediments are subject to resuspension during storm events. While concentrations of these contaminants in current loadings may be expected to decline, the rate of decline in the total mass of these contaminants for the Great Lakes System will occur much more slowly than in systems with shorter hydraulic retention times, or greater sedimentation rates (EPA Region V, Great Lakes National Program Office, Great Lakes Risk Characterization Study, Review Draft, Chicago, IL, 1991). Accordingly, any new discharges of bioaccumulative pollutants of concern will add to food web contamination and prolong the time for the full restoration of beneficial uses of the Great Lakes and unacceptable levels of risk to human, wildlife and aquatic populations which utilize the Great Lakes Basin Ecosystem.

For a number of years, the monitored concentrations of bioaccumulative chemical contaminants have declined in Great Lakes fish. Based on a review of lake trout and coho salmon data collected through 1990, however, it appears that the rate of decline in contaminant concentrations in fish tissue is slowing, and approaching zero (EPA Region V, 1991). Additionally, these data show that fish tissue concentrations are stabilizing at unacceptably high concentrations, despite the decreased loadings resulting from previous regulatory actions. Contaminant concentrations measured in 1990 for PCBs and chlorinated pesticides exceed fish tissue concentrations allowable under current EPA water quality criteria, by several orders of magnitude. If, as the data suggest, a new equilibrium in ambient water quality and fish tissue concentrations is being reached given current loading rates for these pollutants, then substantial further reductions in loadings may be necessary to achieve fish tissue concentrations that would provide for the lifting of fish advisories and bans imposed at present in the Great Lakes region (EPA Region V, 1993).

Finally, in recognizing the sensitive nature of the Great Lakes System, recommendations calling for special, more restrictive measures for toxic pollutants will be consistent with the Great Lakes Water Quality Agreement goal of virtual elimination of persistent toxics, the Great Lakes Governors' Toxics Substance Control Agreement calling for continued reduction of toxics in the Great Lakes System to the maximum extent possible consistent with the Clean Water Act and Great Lakes Water Quality Agreement, and the fishable goal of the CWA. In addition to the purely ecologic benefits associated with reductions in loadings of bioaccumulating toxics, these reductions will generate significant benefits associated with improved opportunities for human uses of the fishery and related resources: increased recreational fishing and hunting opportunities, the potential for commercial fishery expansion, and increased opportunities and values to other recreational users of Great Lakes basin waters.

b. *Nature of Toxic Pollutants Addressed by the GLWQG and*

Implications for Risk Reduction. The benefits of controlling discharges under the proposed Guidance depend on the characteristics of the specific pollutants that are reduced. A number of these pollutants (those associated with control of point source discharges), and associated health and ecological risks, are summarized in Table IX–5. This table illustrates several key points:

i. All compounds are highly persistent, implying that future reductions in loadings will yield long-term benefits. However, for the same reason, current ambient conditions, due to past loadings, are likely to delay the realization of benefits for many years into the future

TABLE IX–5.—SUMMARY OF POTENTIAL CONCERNS

Compound	Persistence	Bio-Accumulation	Bio-Magnification	Human health		Aquatic organisms				Terrestrial organisms			
				Carcinogen (endpoint)	Systemic effects (endpoint)	Fish		Invertebrates		Avian		Mammals	
						Toxicity	D.R.S.	Toxicity	D.R.S.	Toxicity	D.R.S.	Toxicity	D.R.S.
Cadmium	High	High	Only lower trophic levels.	Inhalation only.	High [A]	High	High	High	High	High	High	High	High.
Chromium III	High	Low	No	Not classified	Low [K]	Medium	Low	Medium	Low	Low	Low	Low	Low.
Chromium VI	High	Low	No	Inhalation only.	Low [K]	Medium	Low	Medium	Low	Medium	Low	Medium	Low.
Copper	High	Medium	Low	Not classified	Low [K]	Medium	High	Medium	High	No data	No data	No data	No data.
Cyanide	High	No data	No data	Not classified	High [B]	Medium	No data	Medium	No data	No data	No data	No data	No data.
Mercury	High	High	High	Not classified	High [B]	High	High	High	High	High	High	High	High.
Selenium	High	High	Low	Not classified	Medium [C]	High	High	High	High	High	High	High	High.
Dioxins	High	High	Medium	Probable [D,I]	High [A,B,C,D].	High	High	Medium	Medium	Medium	Medium	Medium	High.
PAHs	High	Only lower trophic levels	Low	Suspected [H,J]	No data [F,G].	High	High	High	High	High	High	High	High.
PCBs	High	High	High	Probable [D]	High [D,E]	High	High	High	High	High	High	High	High.
Phenols	High	Low	Low	No data	Medium [A,D]	Medium	Medium	Medium	Medium	No data	No data	No data	No data.

D.R.S.=Decreased Reproductive Success
[A] Kidney
[B] Central Nervous System
[C] Gastrointestinal.
[D] Liver
[E] Cutaneous.
[F] Hematoboietic.
[G] Lymphoid.
[H] Leukemia.
[I] Lungs.
[J] Stomach.
[K] No adverse effects.

ii. Half the compounds have a relatively high potential for bioaccumulation. The implications are consistent with those raised above with respect to the persistence of the toxics—e.g., even if all future loadings are eliminated and reductions in water column and sediment concentrations are realized, it will take many years for tissue concentrations of these pollutants to decline in impacted biota to the point where residual risks have been minimized.

iii. Dioxin and PCBs are considered probable human carcinogens via ingestion, and both also are associated with systemic (i.e., noncarcinogenic) health risks. Cadmium, cyanide and mercury also are of high concern for systemic human health risks (kidney and central nervous system). While human health risk reductions may not be the primary motivation for the GLWQG, the potential for reducing these risks may be appreciable. Furthermore, because noncarcinogenic effects of the contaminants are presumed to exhibit threshold dose-response functions, it is more difficult to quantify reductions in these types of risks than it is to quantify carcinogenic risks.

iv. Most of the toxics addressed in the GLWQG pose relatively high risk to aquatic and terrestrial organisms, both to the survival of living organisms and their reproductive capacity. These risks imply that the primary benefits of the GLWQG will be related to ecologic concerns. The toxics controlled by the GLWQG pose risks to species of concern and value apart from direct consumptive use for recreation, commercial or other such purposes. For example, bald eagles, osprey, cormorants, mink, otter and other important piscivorous species are likely to face reduced mortality risk and increased breeding success if the levels of the compounds are reduced in the Great Lakes environment. The resulting benefits to society extend beyond more commonly measured consumptive use values and include nonuse or intrinsic benefits, (nonconsumptive and indirect use benefits also are relevant) and option values (which are also considered, in most circles, as a form of use value).

The persistence and toxicity of the compounds to be directly controlled from point sources under the GLWQG have important implications for the benefits analysis. The principal benefits exhibit characteristics that make them less amenable to empirical evaluation than benefits for other EPA actions because: (1) Temporally, most of the direct benefits are likely to be delayed for many years, and (2) structurally, the benefits are largely of the ecologic or nonuse variety.

c. *Overview of Exposed and Sensitive Populations.* The potential for significant health risk reduction benefits exists for certain populations who may be unaware of or ignore fish consumption advisories. For example, Native American tribes in the Great Lakes basin also tend to consume a greater amount of local fish than the general population, and thus are at greater risk than the average exposed population for any associated health effects. East Asian populations such as the Hmong who rely heavily on subsistence fishing, and for many of whom English is a second language, may be particularly vulnerable to exposing themselves to toxic contaminants in fish. Finally, while advisories warn against consumption, many anglers consume recreationally-caught fish in excess of the recommended quantity. All of these populations will benefit from reduced health risks as the concentrations of toxic compounds in fish decrease.

d. *Conclusions.* The benefits associated with the proposed Great Lakes Water Quality Guidance may be substantial due to the significant health and ecologic risks posed by the chemicals addressed by the proposed Guidance, when combined with physical characteristics of the Great Lakes that cause them to be particularly vulnerable to bioaccumulative toxic pollutants. Given the long retention time, low sedimentation, low productivity in the Great Lakes System and presence of self contained, vulnerable populations (and hence the persistence of toxic contaminants in this ecosystem), loadings reductions realized as a result of the GLWQG are expected to have lasting impacts on mortality risk and the reproductive success of many aquatic, avian, and mammalian species of concern. These benefits include increased productivity and protection of biological diversity of Great Lakes species including salmonids and other fish species, cormorants, eagles, osprey, and otters.

Fish and waterfowl consumption advisories are likely to be lifted as concentrations of toxic compounds are reduced. Such actions, and water quality improvements leading to those actions, would result in increased recreational fishing and hunting opportunities and increased values for recreational fishing and hunting days. According to the U.S. Fish and Wildlife Service's 1985 National Survey of Fishing, Hunting, and Wildlife-Associated Recreation (U.S. Department of the Interior, Washington, D.C., 1989) the Great Lakes supported more than 46 million angler days in that year. Even a small increase in the number of angler days or the value associated with improvements in Great Lakes angling would provide significant annual benefits. Other recreational opportunities, including boating, swimming, and wildlife observation would also be expected to be enhanced as water quality and ecosystem health improve. Health risk reduction benefits are likely to be generated through reduced exposure via the following pathways: fish consumption (particularly among subsistence populations relying on Great Lakes fish and wildlife as a primary food source), ingestion of contaminated drinking water, and incidental forms of exposure to contaminants through recreational activities such as swimming. The value of these improvements touch not only direct users of the Great Lakes, but also nonusers who ascribe values to the ecologic benefits resulting from the implementation of the proposed Guidance.

3. Economic Concepts Applicable to Quantitative Benefits Analysis

a. *The Economic Concept of Benefits.* The term economic benefits refers to the dollar value associated with all of the expected direct positive impacts of the Initiative; that is, all GLWQG outcomes that lead to higher social welfare. Conceptually, the monetary value of benefits is embodied by the sum of the predicted changes in consumer (and producer) surplus. These surplus measures are standard and widely accepted terms of applied welfare economics, and reflect the degree of well-being enjoyed by people given different levels of goods and prices (including those associated with environmental quality).

This conceptual economic foundation raises three relevant issues and potential limitations for the benefits analysis of the GLWQG. First, the standard economic approach to estimating environmental benefits is anthropocentric—all benefit values arise from how environmental changes are perceived and valued by humans. Second, benefits of all future outcomes are valued by the present-day human population. Third, all near-term as well as temporally distant future physical outcomes associated with reduced pollutant loadings need to be predicted and then translated into the framework of present-day human activities and concerns.

b. *Benefit Categories Applicable to the GLWQG.* EPA divides the potential benefits associated with the GLWQG into two broad categories: use benefits and nonuse benefits (also referred to as passive use, or intrinsic benefits). The use benefit category can embody both direct and indirect uses of the impacted waters, and the direct use category embraces both consumptive (e.g., fishing) and non-consumptive (e.g., wildlife observation) activities. In most applications to pollutant reduction scenarios, the most prominent use benefit categories are those related to recreational fishing, boating and/or swimming.

Whether or not recreational use benefits reflect society's prime motivation for environmental protection measures is unclear; however, recreational activities are amenable to various non-market valuation techniques (e.g., travel cost models) and, accordingly, have received considerable empirical attention from economic researchers over the past two decades. Thus, there is a considerable body of knowledge relating to recreational fishing and related activities, and these generally indicate that water-based recreation is a highly valued activity in society. Accordingly, many benefits analyses focus on recreational values because they are well understood, there is a large body of empirical research to draw upon, and the associated benefits tend to be quite large.

Improved environmental quality can be valued by individuals apart from any past, present or anticipated future use of the resource in question. Such nonuse (or passive use) values may be of a highly significant magnitude; but the benefit value to assign to these motivations often is a matter of considerable debate. Whereas human uses of a resource can be observed directly and valued with a range of technical economic techniques, non-use values can only be ascertained from directly asking survey respondents to reveal their values. The inability to rely on revealed behavior to ascertain non-use values has led to debates as to whether they exist for applicable changes in environmental quality and, if so, whether they are of an appreciable magnitude relative to use values. As described below, there is reason to anticipate that non-use benefits are relevant and may be appreciable for the proposed Guidance.

Among the more relevant non-use values associated with the GLWQG are ecological benefits associated with decreasing the level of toxic compounds found in Great Lakes waters and sediment. Such ecological benefits are likely to embody reduced risks of direct mortality, and increased reproductive success, in a range of important fish and wildlife species. The species include, but are not limited to, bald eagles, cormorants, and other pisciverous avian species; mink, river otter and other mammalian species that feed on fish and crustaceans; and a wide range of aquatic species such as lake trout and other salmonid species.

4. Limitation of the Benefits Analysis

a. *Causality: Linking the GLWQG to Beneficial Outcomes.* Conducting a benefits analysis for anticipated changes in pollutant loadings and subsequent environmental conditions in the Great Lakes Basin Ecosystem which result from the implementation of the final Guidance is challenging, because predicting the benefits of the GLWQG requires that a chain of events be specified and understood. These relationships span the spectrum of: institutional relationships and policy-making; the technical feasibility of pollution abatement, and facility level decision-making; the physical/chemical properties of receiving streams and their consequent linkages to biologic/ecologic responses in the aquatic environment; and human responses associated with these changes.

The institutional aspects of implementing the GLWQG link the publication of Federal guidance to their ultimate translation by individual States into revised point source discharge permits and controls on nonpoint sources (see discussion in section I.G.10). The revised State permit limits ultimately result in a change in pollutant loadings for targeted contaminants (as well as those removed incidental to the improved wastewater treatment or process changes), from an appropriately defined set of baseline loadings. Such modeling was infeasible within the timeframe available.

b. *Temporal, Spatial and Transfer Issues.* An empirical benefits assessment is a difficult and uncertain undertaking. In the case of the GLWQG, the challenges and limitations are magnified by several important considerations, including (but not limited to):

i. *The Time Path to Ecosystem Recovery From Near-term Reductions in Toxic Loadings.* The toxic compounds relevant to the GLWQG tend to persist in various compartments of the Great Lakes Basin Ecosystem (see discussion in section I.A. of this preamble). Therefore, even the total elimination of additional loadings of these compounds will not immediately alter water column or fish tissue concentrations. A significant portion of the benefits may be realized only in the relatively distant future. An additional issue is the rate at which human behavior and preferences will react to changes in conditions in the Great Lakes System brought about by the GLWQG. If so, the cost-benefit analysis may become more of a forum for raising normative issues (such as intergenerational equity concerns associated with discounting long-term benefit streams) than for resolving the more positive issues of near-term economic efficiency (i.e., whether near-term benefits exceed near-term costs). The influence of discounting on the presentation of benefits and costs for the case study areas demonstrated the relevance of this issue.

ii. *The Geographic Scope of Contamination and of Benefit-generating Activities Throughout the Great Lakes Watershed Ecosystem.* Although the intent of the benefits analysis is to focus on spatially-limited case studies and discharge points, the areal extent of contamination (e.g., PCBs or dioxins bound in sediment) typically is very widespread (even if it originates from a well-defined source at a specific location). The contamination becomes even further dispersed through uptake in the food chain. Thus, the benefits of reducing toxic discharges within the case study watershed are likely to extend beyond the boundaries of the case study (and, likewise, controls adopted and costs incurred beyond the case study boundaries may be necessary to obtain the projected benefits within the study watersheds).

iii. *Existing Data Sources.* The resource-intensive demands associated with developing benefit estimates often leads EPA to use existing data sources and studies to prepare benefit estimates for the case study sites. Applications of benefits transfer techniques in these instances is not new to EPA or this GLWQG, but such applications have not been adequately examined as to their conceptual soundness for purposes of developing EPA policy. EPA and the economics profession have recently begun to take a more rigorous look at these issues.

c. *Baseline and Benefits Attribution Issues.* Among the most important analytic problems faced by this cost-benefit analysis is the need to establish and reconcile the appropriate benefits and costs baselines for the proposed Guidance. To be consistent with the cost analysis, the appropriate benefits baseline must be based upon water quality conditions that would be observed after compliance with the numeric criteria embodied in section 303(c)(2)(b) of the Clean Water Act, and other regulatory and remedial actions in

progress, or anticipated, absent the GLWQG. Therefore, there is an important distinction between present observed conditions, and the conditions that reflect the relevant baseline for the GLWQG.

Benefit analyses can be designed to measure actual or theoretic changes in water quality conditions. In both cases, there must be a well defined baseline condition beyond which the value of water quality improvements can be measured. In this instance, the establishment of a baseline level of water quality conditions upon which the benefits of the GLWQG should be measured must be ascertained to estimate the benefits relevant strictly to the GLWQG. Benefits of improvements expected to occur as a result of current requirements need to be distinguished from the benefits for which will accrue as the results of the implementation of the final Great Lakes Guidance. In some instances, distinguishing between the two is relatively straight forward. At other times, several assumptions must be made and believed to allow the two stages to be distinguished from one another.

One approach for attributing benefits to the GLWQG is to discern how toxic loadings reductions will change from present conditions to the WQG-relevant baseline, and then from this baseline to the post-GLWQG loadings. Unfortunately, the absence of loadings data for all potential sources of toxics (i.e., point and nonpoint sources) does not allow for an assessment of the results of the GLWQG to present conditions. However, point source loadings reduction estimates due to the GLWQG relative to expected loadings that would be observed subsequent to compliance with current regulatory requirements indicate a substantial reduction in toxicity-weighted loadings of pollutants could be achieved. Thus, while the GLWQG will have a significant impact relative to loadings at its baseline, we have no empirical information with which to discern how this reduction compares to differences that may exist between present conditions and the GLWQG-relevant baseline. The absence of this data makes it difficult to attribute benefits to the GLWQG on the basis of changes in loadings with any certainty.

d. *Contingent Valuation Method Issues.* The empirical results presented in the case study analyses utilize benefits estimates from relevant research on water quality improvements. Several of these estimates include results derived from contingent valuation methodology (CVM) (as well as the travel cost methodology (TCM) and other techniques). CVM is an approach in which hypothetical markets are constructed and presented to individuals in a survey format, with the responses used to infer prices and values for the goods and services being evaluated (such as those associated with different levels of environmental quality). Because the CVM approach relies on survey responses to hypothetical conditions and markets, CVM is considered a potentially biased approach to estimating benefits.

In particular, there is an inherent degree of skepticism among some economists regarding the accuracy of results derived from the CVM approach relative to those derived from economic research methods that rely on revealed human behavior, such as TCM. Likewise, where there are no means of relying on revealed behavior as a possible benchmark for accuracy and validity, such as in estimating nonuse values with CVM, the approach has been the subject of considerable debate. The issues surrounding the general validity of the CVM approach are discussed in the RIA, and have been the subject of peer reviewed economics literature for more than a decade (see, for example, R.G. Cummings, D.S. Brookshire and W.D. Schulze, Valuing Environmental Goods, Rowan and Allanheld, Totowa, N.J., 1986; R.G. Cummings and G.W. Harrison, Identifying and Measuring Nonuse Values for Natural and Environmental Resources: A Critical Review of the State of the Art, Final Report, April 1992). Scholarly insights from a broad range of relevant disciplines, including psychology and statistics as well as economics, have also been brought to bear on defining appropriate approaches to developing, implementing, and interpreting state-of-the-art, professionally credible CVM instruments and results (e.g., R.C. Mitchell and R.T. Carson, Using Surveys to Value Public Goods: The Contingent Valuation Method, Resources for the Future, Hopkins University Press, Washington, DC, 1989).

As in any economic research technique, the credibility, accuracy, and robustness of CVM-derived results depend entirely on the research protocol applied by the practitioners in designing and implementing the CVM survey instruments. Poorly designed and executed CVM surveys are likely to generate results that may be biased and misleading. However, careful design and implementation of surveys allow researchers to test for (and account for) potential biases and embedded values. In brief, each CVM study must be evaluated and interpreted on its own merits; there are many high quality CVM research efforts that provide credible and reliable information. Accordingly, among numerous academic and applied economic researchers, CVM is recognized as capable of providing robust and credible benefits estimates.

Indeed, a NOAA Blue Ribbon Panel review (K. Arrow, R. Solow, P.R. Portney, E.E. Leamer, R. Radner, and H. Schuman, Report of the NOAA Panel on Contingent Valuation, U.S. Department of Commerce, National Oceanic and Atmospheric Administration, Rockville, Maryland, 1993) of CVM to measure nonuse values concluded that CVM can produce reliable estimates for use in the litigation process to determine natural resource damages. The panel set forth a number of guidelines for CVM surveys. The guidelines address survey design (including the recommendation of a personal interview format); elicitation format (including the recommendation of a conservatively designed referendum eliciting willingness to pay (WTP) and checks on understanding and acceptance); and additional issues that CVM surveys should explicitly address (e.g., the warm glow of giving effect). The Panel maintained that use of these guidelines will generate more reliable results.

The NOAA panel evaluated CVM as a means of estimating nonuse values for use in litigation to determine the liability of a specific party rather than for use in a public policy setting. Thus, the applicability of the standards set by the Panel to analysis of regulatory impacts should be evaluated considering that the estimates are used in an informational context, to compare benefits to costs. Failure of the CVM studies utilized in the case studies analyses to conform to all of the NOAA recommendations should therefore not automatically preclude them from being considered as a source for benefits information.

i. *Using CVM to Estimate Use (Recreational) Benefits.* The issues associated with using CVM for use values (e.g., recreational benefits) are somewhat distinct from those of estimating nonuse values. Since recreational activities are amenable to various non-market valuation techniques, one means of assessing the accuracy of CVM results for estimating use values is to compare results of CVM research for use benefits with those for other valuation methods which rely on revealed behavior (e.g., TCM, hedonic pricing). Examples can be found in the comparative reviews of R.G. Walsh, D.M. Johnson, and J.R McKean

(Nonmarket Values From Two Decades of Research on Recreation Demand, Advances in Applied Microeconomics, Vol. 5, V. K. Smith and A. N. Link (eds), JAI Press Inc.,1990); Cummings, Brookshire, and Schulze (1986); and A. M. Freeman (The Economics of Valuing Marine Recreation: A Review of the Empirical Evidence, Draft Report to OPPE/USEPA, Washington, D. C.,1992). These studies reveal that the accuracy of both types of methodologies depends heavily on the study design, and both methodologies can produce wide ranging estimates as a result. Furthermore, CVM studies of recreation use benefits have performed reasonably well when compared to the available evidence from travel behavior, actual cash transactions, and controlled laboratory experiments.

ii. *Using CVM to Measure Nonuse Values.* CVM provides a method for directly eliciting nonuse values where there do not appear to be direct market transactions or indirect methods based on market behavior available to reveal these values. Indeed, CVM's greatest asset is its potential to measure any benefit category. As is the case with use values, efforts to measure nonuse values by CVM must be thoughtfully conceived, well designed, and carefully implemented. Where testable (recreation values only), estimates for use values from high quality CVM studies have been found to compare favorably with results obtained from other accepted valuation methods. Providing similar test results for nonuse values has proved difficult, and thus critics of the CVM approach have questioned the reliability of CVM in estimating nonuse values for which alternate measures of comparison are difficult, if not impossible, to construct. While the NOAA Panel found the criticisms of CVM to take on added importance in light of this absence of alternate measures with which to compare the estimates, it recognized that this problem would be inherent in any method of estimating nonuse values.

5. Cost-Effectiveness of the Proposed Guidance at Three Sites

For each of the three case studies (Fox River/Green Bay, WI; Saginaw Bay, MI; and Black River, OH), loadings reductions were estimated for cost scenarios 1 and 2 using the approach outlined earlier. These loadings were then converted into toxicity-weighted pounds (or pounds-equivalents). Pounds-equivalent per day were multiplied by 365 days to obtain annual reductions in the loadings. Total annualized costs for Scenarios 1 and 2 were then divided by the total annual reductions in toxicity-weighted pounds to obtain $ per pound-equivalent.

The cost-effectiveness values for all four Scenarios in the Fox River case study range between $0.80 per pound-equivalent and $4.02 per pound-equivalent over the baseline. The cost-effectiveness for the most likely scenario, Scenario 2, is $1 46 per pound equivalent. The cost-effectiveness for the Saginaw Bay case study is between $1.70 per pound-equivalent and $22.50 per pound-equivalent over the baseline for all four scenarios. The cost-effectiveness for the most likely scenario is about $4.62 per pound-equivalent over the baseline. The cost-effectiveness of all four scenarios for the Black River case study range between $8.08 per pound-equivalent and $164.73 per pound-equivalent over the baseline. The cost-effectiveness of the most likely scenario is $22 41 per pound-equivalent. The results of these analyses are presented in more details in the Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance.

6. Future Analysis

The discussion above provides useful insights into the potential impacts of the proposed Guidance. It also indicates areas in which additional analysis and research may be useful for strengthening our understanding of the GLWQG, the Great Lakes Basin Ecosystem, and policy analysis in general. Areas which the EPA will consider for future analyses include:

a. Obtain more information and conduct more sophisticated analyses to estimate the appropriate baseline for analyzing the GLWQG, and the improvements beyond that baseline attributable to the GLWQG. These efforts might focus on pollutant loadings, the physical/chemical properties of receiving waters, and aquatic ecosystem impacts. This would help define more reliable means for assigning benefits to the GLWQG than has been attempted in these case studies.

b. Expand the effort to encompass a broader array of case study sites. The benefits and costs of water quality improvements are highly site-specific. The analysis can be broadened to portray this, and establish a framework by which information from case studies can be used to represent aggregate benefits of the GLWQG.

c. Incorporate Monte Carlo or Other Sensitivity Analysis Techniques into the analysis to more clearly and insightfully portray the uncertainties in the results, and the extent to which the assumptions necessary to conduct the analysis influence the outcomes.

d. Broaden the perspective of the case studies to examine and properly account for the full suite of environmental actions necessary to realizing important threshold-like improvements in water quality. Benefits typically accrue only when discrete changes in the environment are realized, and such changes generally arise as a joint product of several efforts implemented over a course of time (e.g., nonpoint source controls as well as point source controls may both be required to attain fishable waters). The case study approach is a valuable tool for clearly identifying and assessing these multiple program and associated benefits apportionment issues.

e. Define, assess and interpret options for explicitly addressing the issue of how to portray and account for long-term ecologic benefits in a benefit-cost analysis such that it appropriately balances normative concerns within a positive analytic paradigm.

The results of additional analyses will be placed in the record.

This proposed rule was submitted to the Office of Management and Budget for review as required by Executive Order 12291.

X. Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.*, EPA must prepare a Regulatory Flexibility Analysis for regulations having a significant impact on a substantial number of small entities. The RFA recognizes three kinds of small entities and defines them as follows:

—Small governmental jurisdictions—any government of a district with a population of less than 50,000.
—Small business—any business which is independently owned and operated and not dominant in its field as defined by Small Business Administration regulations under Section 3 of the Small Business Act.
—Small organization—any not-for-profit enterprise that is independently owned and operated and not dominant in its field.

As discussed in section IX above, small facilities are projected to incur less than $3,300 per facility to comply with the requirements in the proposed Guidance. These costs are not expected to impose economic burdens on small facilities. Accordingly, I certify pursuant to 5 U.S.C. 605(b) that the proposed Guidance, if implemented, will not have a significant impact on a substantial number of small entities and that a Regulatory Flexibility Analysis,

therefore, is unnecessary. After the proposal, EPA is planning to conduct a more detailed economic analysis and will reconsider this determination, if warranted.

XI. Paperwork Reduction Act

The information collection requirements in this proposed rule have been submitted for approval to OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.* EPA has prepared an Information Collection Request (ICR) document (ICR No. 1639.01). Copies of the ICR may be obtained by writing Sandy Farmer, Information Policy Branch, EPA, 401 M St., SW. (PM–223Y), Washington, DC 20460, or by calling (202) 260–2740.

The public reporting burden for this collection of information is estimated to be 69,283 hours for the 3,795 permittees, or an average 18.2 hours.

Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Chief, Information Policy Branch, PM–223Y, U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503. The final rule will respond to any OMB or public comments on the information collection requirements contained in this proposal.

XII. Judicial Review of Provisions not Amended

In some situations, EPA is proposing renumbering or other editorial changes to regulations that have already been promulgated, or to provide for ease in reading proposed changes is repeating an entire section, including the portions not changed. The proposal and promulgation of these regulations does not provide another opportunity to seek judicial review on the substance of these regulations.

XIII. Supporting Documents

All documents that are referenced in this preamble are available for inspection and photocopying in the administrative record for this rulemaking at the address listed at the beginning of this preamble. A reasonable fee will be charged for photocopies.

The documents listed below are also available for a fee upon written request or telephone call to the National Technical Information Center (NTIS), U S. Department of Commerce 5285 Port Royal Road, Springfield, VA 22161 The toll free number is 800–336–4700 and the local number is 703–487–4650 Alternatively, copies may be obtained for a fee upon written request or telephone call to the Educational Resources Information Center/ Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/ CSMEE), 1200 Chambers Road, room 310, Columbus, Ohio 43212 (phone number: 614–292–6717). When ordering, please include the NTIS or ERIC/CSMEE accession number.

A. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Aquatic Life in Ambient Water. NTIS Number: PB93–154656. ERIC Number: 3900.

B. Great Lakes Water Quality Initiative Technical Support Document for the Procedure to Determine Bioaccumulation Factors. NTIS Number: PB93–154664. ERIC Number: 3910.

C. Derivation of Proposed Human Health and Wildlife Bioaccumulation Factors for the Great Lakes Initiative. NTIS Number: PB93–154672. ERIC Number: 3920.

D. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Human Health. NTIS Number: PB93–154680. ERIC Number: 3930.

E. Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values. NTIS Number: PB93–154698. ERIC Number: 3940.

F. Technical Support Document: Establishment of Ambient Screening Values Under the Great Lakes Water Quality Initiative. NTIS Number: PB93–154706. ERIC Number: 3950.

G. "Analysis of Acute and Chronic Data for Aquatic Life," Host, G.E., R.R. Regal, and C.E. Stephan, 1–4–91 draft. NTIS Number: PB93–154714. ERIC Number· 3960.

H. Great Lakes Water Quality Initiative Criteria Documents for the Protection of Wildlife. NTIS Number: PB93–154722. ERIC Number: 3970.

I. Assessment of Compliance Costs Resulting from Implementation of the Proposed Great Lakes Water Quality Guidance. NTIS Number: PB93–154730. ERIC Number· 3980

J. Regulatory Impact Analysis of the Proposed Great Lakes Water Quality Guidance. NTIS Number· PB93–154748. ERIC Number· 3990.

Appendix to the Preamble—Great Lakes Water Quality Initiative Technical Support Document for Wildlife Criteria

Note: This appendix to part 132 contains background material and material intended to clarify portions of the regulation. It does not establish any additional regulatory requirements.

I. Introduction

The waters of the Great Lakes System provide vital resources not only to support numerous critical human activities and habitat for aquatic organisms, but also to sustain viable mammalian and avian wildlife communities. In order to assure that the quality of the waters in the System are adequate to support these uses, specific water quality criteria need to be set.

The purpose of establishing water quality criteria for wildlife is to determine surface water concentrations of toxicants that will remain protective of avian and mammalian wildlife populations that utilize waters of the Great Lakes System as a drinking and/ or foraging source. Specifically, each criterion is the highest calculated aqueous concentration of a toxicant which causes no significant reduction in the viability or usefulness (in a commercial or recreational sense) of a population of exposed animals over several generations. For the purpose of these regulations, this concentration is called the Great Lakes Wildlife Criterion (GLWC).

Ideally, a safe concentration of a given pollutant would be calculated for every species and the GLWC would be determined based on the distribution of these values across all species (an approach similar to that used in deriving criteria to protect aquatic life, Stephan et al., 1985). Therefore, an approach similar to that proposed to derive a noncancer human health criterion (section III.C.3 of appendix C to part 132 of this rule, Methodologies for Development of Human Health Criteria and Values) was used in which representative wildlife species were selected to establish the basis for employing interspecies uncertainty factors for extrapolation of toxicity data and to define specific exposure parameters. Five Great Lakes basin wildlife species representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience significant exposure to contaminants through the aquatic food web were identified. These species are the bald eagle, osprey, belted kingfisher, mink, and river otter. A Wildlife Value (WV) is calculated for each representative species (which is a safe concentration of a given pollutant) and then the geometric mean of these values within each taxonomic class is determined. The GLWC is the lower of two class-specific means.

To derive the WVs from which the GLWC is determined, scientific literature for the toxicant of concern is reviewed for mammalian and avian

toxicity studies that meet the minimum toxicity database requirements. A tiered approach is used in the derivation of these criteria. Tier I values are developed for chemicals with databases providing a high level of certainty in quantifying concentrations at which adverse effects may be experienced by the avian and mammalian wildlife communities. EPA is proposing four specific Tier I criteria that will be applicable across the Great Lakes System. States and Tribes will be expected to adopt into regulation these criteria (or more stringent values). They will also be expected to adopt the procedure for developing Tier I values for additional substances. EPA encourages States and Tribes to adopt these Tier I values as criteria.

Chemicals with less extensive data, or where the level of certainty is less, are subject to Tier II values. States and Tribes will be expected to adopt, by regulation, the procedure for developing Tier II values, rather than the numeric values the procedure generates.

II. Calculation of Wildlife Values for Tier I Criteria and Tier II Value Development

A. Derivation of Equation

The equation used to calculate Wildlife Values (WV), and ultimately the GLWC, has both a hazard and exposure component. The hazard component contains the NOAEL—the highest tested dose of a substance which does not result in an observed adverse effect. The exposure routes considered in this derivation are food and water ingestion. The intake level is dependent on organism size and therefore it is scaled to body weight. The total toxicant intake through these exposure routes is determined and then set equal to the NOAEL as follows:

Toxicant intake through drinking water=$(WV \times W_A)/Wt_A$ (Equation 1)

Toxicant intake through food=$(WV \times F_A \times BAF)/Wt_A$ (Equation 2)

Where:

WV=Wildlife value in milligrams of substance per liter (mg/L).

W_A=Average daily volume of water consumed in liters per day (L/d) by the representative species identified for protection or the species identified as requiring greater protection.

F_A=Average daily amount of food consumed in kilograms per day (kg/d) by the representative species identified for protection or the species identified as requiring greater protection.

BAF=Aquatic life bioaccumulation factor for wildlife in liters per kilogram (L/kg). Chosen using guidelines for wildlife presented in appendix B to part 132 of this rule, the Methodology for Development of Bioaccumulation Factors.

Wt_A=Average weight in kilograms (kg) for the representative species identified for protection or the species identified as requiring greater protection.

Equations one and two are combined to yield Equation three.

$$NOAEL > (WV \times W_A)/Wt_A + (WV \times F_A \times BAF)/Wt_A \quad \text{(Equation 3)}$$

Where:

NOAEL=No observed adverse effect level in milligrams of substance per kilogram of body weight per day (mg/kg – d) as derived from mammalian or avian toxicity studies.

Factoring and rearranging produces:

$$WV < \frac{NOAEL \times Wt_A}{W_A + [F_A \times BAF]} \quad \text{(Equation 4)}$$

To account for differences in toxicity among species, the NOAEL is multiplied by the species sensitivity factor, SSF. The final equation for the WV is:

$$WV = \frac{[NOAEL \times SSF] \times Wt_A}{W_A + [F_A \times BAF]} \quad \text{(Equation 5)}$$

B. Weight of the Test Animal, Representative Species, or Species Requiring Greater Protection

The weight of the test animal may be needed to convert the NOAEL determined in the study to the correct units for use in the equation to derive a wildlife value. If a species is identified as requiring greater protection and is not one of the representative species, its weight is needed for calculation of the GLWC. If this information is not given in the chosen study, the average weight of the test species shall be determined from available literature, including, if necessary, metabolic rate models, such as those presented by Nagy (1987), and discussed further, below.

C. Drinking and Feeding Rates for the Test Animal or Species Requiring Greater Protection

A feeding and drinking rate for a species identified as requiring greater protection and which is not one of the representative species identified for protection may also be needed for calculation of the GLWC. These rates are needed to accurately predict exposure. When consumption rates are given in the study of choice, they may be substituted directly into the equation. If this information is not available from the chosen toxicity study, it shall be obtained from other appropriate literature concerning the species. In some instances, however, this information is not available directly and needs to be estimated. The following

reference may be consulted for studies done with domestic laboratory animals: Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition).

When insufficient data exist for other mammalian or avian species, the allometric equations presented in appendix D to part 132 should be used to approximate the needed feeding or drinking rates. These equations were adopted from Calder and Braun (1983), and Nagy (1987).

When replicated data exist, best professional judgement will be used in the selection of a single value. Barring that, the geometric mean of the data points will be utilized as the representative value.

III. Parameters of the Hazard Component of the Wildlife Criteria Methodology

A. Minimum Toxicity Database for Tier I Criteria Development

The 90-day requirement for mammalian studies and the 28-day requirement for avian studies are to ensure that the toxicity data on which a wildlife criterion is based exceeds an acute exposure, which may underestimate the potency a compound would have following a chronic exposure. These minimum test length requirements are to be applied to both field and laboratory studies.

B. Minimum Toxicity Database for Tier II Wildlife Value Development

For those substances for which Tier I criteria cannot be derived, all data from avian and mammalian species may be considered in the development of Tier II values. Subchronic or chronic toxicity data shall be used whenever available to derive a no observable adverse effect level (NOAEL) for Tier II values. There are two major differences in data requirements for Tier II values: (1) The minimum database requirements presented for the derivation of a Tier I wildlife criteria must only be met for one of the two taxonomic classes in order to derive a Tier II wildlife value; and (2) a Tier II value may also be based on a mammalian study which fulfills the requirements set forth for Tier I criteria excepting it may have only a 28-day duration.

LD50 and eight-day LC50 data may be used in support of subchronic and chronic toxicity data; however, neither a Tier I criteria nor a Tier II value shall be calculated solely on the basis of LD50 or eight-day LC50 data.

C. LOAEL to NOAEL Extrapolations

If a NOAEL in proper units is available from the scientific literature, it may be substituted directly into the equation. In many instances, however, a NOAEL is unavailable and a LOAEL is available for a particular animal. In these instances the LOAEL must be adjusted to estimate a NOAEL and converted to proper units before being substituted into the equation.

The LOAEL is adjusted by dividing by an uncertainty factor which typically ranges in value from 1.0 to 10 to lower the LOAEL into the range of the NOAEL. Experimental support of this concept is provided by Weil and McCollister (1963). A discussion and endorsement of this concept can be found in Stokinger (1972) and Dourson and Stara (1983). In addition, this concept is endorsed by EPA in the **Federal Register** for Water Quality Criteria Documents (45 FR 79353–79354, November 28, 1980) and in the National Drinking Water Regulations (50 FR 46944–46946, November 13, 1985). Additional discussion on the use of a LOAEL to NOAEL uncertainty factor and the determination of its magnitude is also provided in appendix A to the Great Lakes Water Quality Initiative (GLWQI) Technical Support Document for Human Health Criteria and Values, which is available in the administrative record for this rulemaking.

D. Subchronic to Chronic Extrapolations

In certain instances where only subchronic data are available, a subchronic to chronic uncertainty factor may be used to account for the uncertainty in extrapolating from a subchronic NOAEL to a chronic NOAEL. The value of the uncertainty factor is within the range of 1.0 to 10, depending on the dose-response of the adverse effect. The subchronic NOAEL is divided by the uncertainty factor. This factor may be used when assessing highly bioaccumulative chemicals, where toxicokinetic considerations suggest that a bioassay of limited length may underestimate hazard. This concept and the use of a 10-fold uncertainty factor is endorsed by EPA in the **Federal Register** for Water Quality Criteria Documents (45 FR 79353–79354, November 28, 1980) and in the National Drinking Water Regulations (50 FR 46944–46946, November 13, 1985). Additional discussion on the use of a subchronic to chronic uncertainty factor is also provided in appendix A to the Great Lakes Water Quality Initiative Technical Support Document for Human Health Criteria and Values, which is available in the administrative record for this rulemaking.

E. Species Sensitivity Factor

The NOAEL shall be adjusted to accommodate differences in interspecies toxicity with the use of an uncertainty factor. This adjustment may be necessary since the toxicity information upon which a criterion is developed will not necessarily be based on a study using the representative wildlife species or the species identified as requiring greater protection. In order to provide protection for the representative species or the species requiring greater protection, an uncertainty factor called the species sensitivity factor (SSF) shall be used, the value of which shall be based on the physicochemical, toxicokinetic and toxicodynamic properties of the substance in question. The value of the SSF shall also be based on the amount and quality of available toxicological data—both the duration and quality of available studies and the diversity of species for which data is available. Toxicity information for chemicals which operate by the same mode of action can also be considered in deriving the SSF for a given chemical. The SSF is not intended to adjust for potential differences with regard to body weight and food and water consumption rates between the test species and the representative species or species requiring greater protection. The factor selected shall reflect the uncertainty with which the available toxicity data are appropriate for the representative species or the species requiring greater protection.

For Tier I wildlife criteria, the SSF generally shall be used for extrapolating toxicity data across species within a taxonomic class and have a value within the range of 0.01 and 1.0. Use of a SSF outside of this range is prohibited unless approved by EPA. An interclass extrapolation employing a SSF may be used for a specific chemical if it can be supported by a validated biologically-based dose-response model, incorporating acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

For Tier II wildlife values, interclass extrapolations are permitted. Because of the uncertainties in performing interclass extrapolations, the SSF for calculating Tier II values may not be greater than 1.0 but may be lower than 0.01 without requiring a written justification. It is stressed that Tier II values are by definition and design conservative. Tier II values can be derived when subchronic or chronic data are available from only one taxonomic class; however, because there

is more uncertainty in performing interclass extrapolation, a more conservative SSF may be applied.

To determine the proper range for the species sensitivity factor, LD50 data were reviewed for approximately 50 chemicals and chronic toxicity data were reviewed where available. Table I of the annex contains LD50 data for nine pesticides, PCBs (Aroclor 1242) and 2,3,7,8-tetrachlorodibenzo-p-dioxin. This table demonstrates how toxicity from certain chemicals differs among species. Table II of this annex contains chronic toxicity data for organomercury compounds in mammalian species. These data support both the use of an interspecies uncertainty factor and the range of the SSF established within this procedure.

In application, a database containing both chronic and reproductive/developmental data for a diversity of species may require a SSF of between 0.1 and 1.0. If these data are from numerous species and represent the most sensitive mammalian and avian species, the SSF may be equal to 1.0.

IV. Parameters of the Exposure Component of the Wildlife Criteria Methodology

A. Bioaccumulation Factors

A bioaccumulation factor (BAF) is necessary to estimate the concentration of the chemical in the wildlife food source based on its concentration in the water source. The procedure to derive the BAF is specified in appendix B to part 132 of this rule. This methodology specifies that, in general, trophic level three and four BAFs are used in the derivation of wildlife values, although options to use plant or other trophic level BAFs are permitted based on the identification of species requiring greater protection which are not obligate piscivorous or are not likely to consume only fish species at trophic level three or four.

V. Determination of Species Identified for Protection and Associated Exposure Parameters

Wildlife exposure to environmental contaminants in aquatic systems can be quite variable depending on natural history characteristics of species and on animal physiology. Furthermore, for most species there are few data to estimate exposure in nature (e.g., ingestion rates of natural foods, field metabolic rates). The procedure outlined below integrates appropriate exposure information for a broad array of species with variable exposure scenarios and was used to determine representative species identified for protection in deriving the Great Lakes Wildlife Criteria. This analysis also supports the WV derivation procedure which reflects an approach similar to the human non-carcinogen water quality criteria derivation procedure.

A. Selection of Species Identified for Protection

The analysis described in this section was performed to determine representative avian and mammalian species of the Great Lakes basin which are likely to experience significant exposure to contaminants in aquatic ecosystems through the food chain. As a consequence, emphasis is on species with foraging behaviors and trophic levels of their forage sources which suggest high exposure to contaminants. Therefore, the wildlife species of primary concern are piscivorous.

In general, small endotherms have a higher ingestion rate relative to body mass than large endotherms, because small animals generally have a larger surface area to volume ratio and lose proportionately more energy as heat. This suggests that small animals would be exposed to contaminants to a greater degree than large animals, and would always be at a higher level of risk. However, small piscivorous are generally size-limited predators and feed on smaller fish in a lower trophic status than larger piscivorous. Since the concentration of bioaccumulative pollutants is usually less at lower trophic levels, it can not be assumed that small animals have a greater exposure. Therefore, to adequately predict exposure, information on animal size, food habits, and behavior is needed.

Determinations were made of representative species that reside in the Great Lakes basin, based on animal size (small, medium, and large) and foraging style. Animals with different foraging styles may also have different morphologies and activity patterns that ultimately influence food or water ingestion rates and other factors that determine exposure to contaminants.

1. *Selection of Avian Species.* Piscivorous avian species can be classified into three general types of foraging styles; raptorial predators, diving and swimming predators, and wading, "sit-and-wait" predators. Some species which reside in the Great Lakes basin and exhibit each of these foraging styles are listed here:

a. Raptorial: Bald eagle, osprey, kingfisher and common tern;

b. Diving: Double-crested cormorant, common loon, common merganser and red-breasted merganser; and

c. Wading: Great blue heron and green-backed heron.

Exposure data with sufficient detail to make reasonable exposure estimates for six Great Lakes basin piscivorous birds was obtained: Bald eagle, osprey, common merganser, common loon, double-crested cormorant and belted kingfisher. These species represent two of the three foraging styles identified. Analysis of these data indicate that the ingestion rates are proportional to the animal mass and the differing foraging styles do not contribute to differences in the ingestion rate. A representative sample of the variability in bird exposure to contaminants in water can be gained by calculating WVs for the three raptorial species (eagle, osprey and kingfisher) which represent the range and extremes in body size. The additional data, since it is only for a small number of species, was not used because it could skew the distribution.

2. *Selection of Mammalian Species.* Two mammals were identified in the Great Lakes basin which are piscivorous and therefore likely to experience significant exposure to contaminants in aquatic food chains—the mink and river otter. The two species have different body sizes (adult otters are six-to-eight times larger than adult mink), and different food habits. Wildlife Values should be calculated for both mammal species. The mink has a larger food ingestion rate relative to body size than the otter. However, it is unlikely that mink have a diet that is comprised solely of fish from the higher trophic level as is predicted for the otter. Therefore, calculating WVs for both mammals may account for the variability in exposure that likely occurs in mammals.

B. Derivation of Exposure Parameters and Body Weights for Species Identified for Protection

1. *Bald Eagle (Haliaeetus leucocephalus).* Adult eagles weigh from 3.0 to 6.3 kg with an average adult weighing about 4.5 kg. (Bortolotti, 1984; Stalmaster and Gessaman, 1984; Palmer, 1988).

There have been several estimates of food ingestion rates of captive and free-ranging eagles. Stalmaster and Gessaman (1982) found that captive eagles consumed about 9.2 percent of their body mass in fish each day (approximately 414 g/d). However, by weighing fish carcasses before and after they were fed upon by free-ranging eagles, Stalmaster and Gessaman (1984) estimated that eagles wintering on the Nooksack River, WA, consumed about 490 g of fish each day. Using models produced by Gessaman and Stalmaster

(1984), Craig et al. (1988) estimated that adult eagles wintering along the lower Connecticut River, CT, consume about 520 g of food per day. Therefore, it is assumed that a typical adult eagle consumes about 500 g of fish per day.

The water ingestion rate is derived from the allometric equation presented in appendix D to part 132 and is 0.16 L/d.

2. *Osprey (Pandion haliatus).* Adult ospreys weigh from 1.1 kg to 2.0 kg with a typical adult weighing approximately 1.5 kg (Newell et al., 1987; Palmer, 1988; Poole, 1989).

As reviewed by Palmer (1988), adult osprey consume 286 kcal/d. Assuming the metabolizable energy in fish is approximately 1 kcal/g (Palmer, 1988; Stalmaster and Gessaman, 1982), osprey require 286 g of fish per day. A review of data for European Ospreys, summarized by Palmer, 1988, suggested that food requirements were about 300 to 400 g/d. Nagy (1987) presents models to calculate field metabolic rates (FMRs) of birds and mammals based on body weights. The equation for calculating the FMR (in kcal/bird-d) of a non-passerine bird is as follows:

$$\log FMR\ (kcal/bird\text{-}d) = 0.0594 + 0.749 \log Wt\ (g)$$

where Wt is in g, wet weight.

The Nagy (1987) model predicts that osprey require 274 g of fish per day, assuming osprey weigh 1500 g and the metabolizable energy in fish is 1 kcal/g. Also, Newell et al. (1987) estimated that osprey would require 300 g/d assuming birds consume 20% of their body weight each day. Therefore, it appears that a reasonable estimate of food ingestion rate for adult ospreys is approximately 300 g/d.

The water ingestion rate is derived from the allometric equation presented in appendix D to part 132 of this rule and is 0.077 L/d.

3. *Belted Kingfisher (Ceryle alcyon).* The average adult belted kingfisher weighs approximately 0.15 kg (Fry, 1980; Dunning, 1984).

Alexander (1977) reviewed the literature and estimated that adult Belted Kingfishers may consume up to 50 percent of their body weight in fish each day. This would equate to approximately 75 g/d. Since this was an estimate, the Nagy (1987) model was applied to calculate the FMR in kcal/d for a non-passerine bird:

$$\log FMR\ (kcal/bird\text{-}d) = 0.0594 + 0.749 \log Wt\ (g).$$

Assuming kingfishers weigh 150 g, and that the metabolizable energy in fish is 1 kcal/g (Stalmaster and Gessaman, 1982; Palmer, 1988), the Nagy model predicts that birds would require about 50 g/d. Therefore, a reasonable estimate of the kingfisher food ingestion rate would be about 75 g of fish per day.

The water ingestion rate is derived from the allometric equation presented in appendix D to part 132 and is 0.017 L/d.

4. *Mink (Mustela vison).* Adult male mink range from 0.9 to 1.6 kg, and females range from 0.6 to 1.1 kg (Linscombe et al., 1982). Therefore, it is assumed that an average adult mink has a body mass of 1.0 kg (see also Newell et al., 1987).

Estimates of food ingestion rates of captive mink range from about 12 percent to 16 percent of the adult body weight per day (Aulerich et al., 1973; Bleavins and Aulerich, 1981). Therefore, it will be assumed that a one kg adult mink consumes about 150 g of food per day (Aulerich et al., 1973; Newell et al., 1987).

The water ingestion rate is derived from the allometric equation presented in appendix D to part 132 and is 0.099 L/d.

5. *River Otter (Lutra canadensis).* Adult otters range from 5 kg to 15 kg, with a typical adult weighing 8 kg (Lauhachinda, 1978; Toweill and Tabor, 1982).

Toweill and Tabor (1982) reviewed two studies reporting food ingestion rates of captive otters. North American otters were reported to require about 700 to 900 g of prepared food each day, while European otters consumed 900 to 1000 g of live fish each day. Therefore, it is assumed that otters consume about 900 g of food per day.

The water ingestion rate is derived from the allometric equation presented in appendix D to part 132 and is 0.64 L/d.

C. Derivation of Dietary Trophic Levels for Species Identified for Protection

1. *Bald Eagle (Haliaeetus leucocephalus).* Bald Eagles are known to consume a variety of foods including fish, waterfowl, small mammals, and carrion. However, if available, fish are their principal food and large fish may make up 100 percent of their diet (Newell et al., 1987; Palmer, 1988; Kozie and Anderson, 1991). Therefore, it is assumed that eagles consume only trophic level 4 fish.

2. *Osprey (Pandion haliatus).* The diet of Osprey is almost 100 percent live fish, concentrating on fish weighing 150–300 g (Palmer, 1988 and Poole, 1989). Therefore, it is assumed that Osprey are consuming only trophic level 3 fish.

3. *Belted Kingfisher (Ceryle alcyon).* Kingfishers may eat a variety of foods including fish, amphibians, and insects. However, small fish are known to comprise roughly 90 percent of their total diet (Alexander, 1977). Therefore, it is assumed that kingfishers have a diet of only trophic level 3 fish.

4. *Mink (Mustela vison).* Mink are opportunistic carnivores (Linscombe et al., 1982); however, aquatic organisms sometimes comprise almost 100 percent of their diet with fish usually making up less than 50 percent of their total intake (Aulerich, 1973; Alexander, 1977; Linscombe et al., 1982; Newell et al., 1987). It is assumed that the diet of mink foraging in habitats comprising the shores of the Great Lakes and major tributaries is made up of trophic level 3 fish.

5. *River Otter (Lutra canadensis).* The bulk of the otter's diet is composed of fish (typically greater than 90 percent) with other aquatic organisms making up lesser portions (Toweill and Tabor, 1982; Newell et al., 1987). It is assumed that otters consume a diet composed of 50 percent trophic level 3 and 50 percent trophic level 4 fish.

TABLE I.—SENSITIVITY OF SPECIES BASED ON LD_{50} Data

Chemical and Species	LD_{50} (mg/kg)	[95% Confidence Interval]
Aldrin:		
Fulvous whistling duck	29.2	[22.2–38.4]
Mallard	520	[229–1,210]
Bobwhite	6.59	[5.00–8.66]
Pheasant	16.8	[14.1–20.0]
Mule Deer	18.8–37.5	

TABLE I.—SENSITIVITY OF SPECIES BASED ON LD_{50} Data—Continued

Chemical and Species	LD_{50} (mg/kg)	[95% Confidence Interval]
Chlordane:		
Mallard	1,200	[954–1,510]
California Quail	14.1	[9.14–21.7]
Pheasant	24.0–72.0	
DDT:		
Bullfrog	72,000	
Mallard	72,240	
California Quail	595	[430–825]
Japanese Quail	841	[607–1,170]
Pheasant	1,334	[894–1,990]
Sandhill Crane	71,200	
Rock Dove	74,000	
Dieldrin:		
Canada Goose	<141	
Fulvous Whistling Duck	100–200	
Mallard	381	
California Quail	8.78	[6.47–11.9]
Japanese Quail	69.7	[40.0–121]
Pheasant	79.0	[21.6–289]
Chukar	25.3	[15.2–42.2]
Gray Partridge	8.84	[1.24–62.8]
Rock Dove	26.6	[19.2–36.9]
House Sparrow	47.6	[34.3–66.0]
Mule Deer	75–150	
Domestic Goat	100–200	
Endrin:		
Mallard	5.64	[2.71–11.7]
Sharp Tailed Grouse	1.06	[0.552–2.04]
California Quail	1.19	[0.857–1.65]
Pheasant	1.78	[1.12–2.83]
Rock Dove	2.0–5.0	
Mule Deer	6.25–12.5	
Domestic Goat	25.0–50.0	
Hexachlorobenzene:		
Mallard	71,414	
Pheasant	118	[93.6–148]
Parathion:		
Fulvous Whistling Duck	0.125–0.250	
Mallard	2.40	[1.67–4.01]
Mallard	1.90	[1.37–2.64]
Mallard	2.34	[1.88–2.92]
Mallard	1.44	[1.13–1.83]
Mallard	1.44	[1.16–1.80]
Mallard Duckling (MM)	0.898	[0.770–1.05]
Sharp Tailed Grouse	5.56	[3.46–9.24]
California Quail	16.9	[12.2–23.5]
Japanese Quail	5.95	[3.38–10.5]
Pheasant	12.4	[10.1–15.2]
Pheasant	>24.0	
Chukar	24.0	[16.8–34.2]
Gray Partridge	16.0	[4.00–64.0]
Rock Dove	2.52	[1.82–3.50]
House Sparrow	3.36	[2.43–4.66]
Mule Deer	22.0–44.0	
Domestic Goat	28.0–56.0	
PCB (Aroclor 1242):.		
Mallard Duck	2,098	
Pheasant	2,078	
Mink	1.0–8.6	
Ferret	>20	
Rat	0.8–11.0	
Rabbit	8.7	
Temephos:		
Bullfrog	>2,000	
Mallard	79.4	[38.5–163]
California Quail	18.9	[15.0–23.8]
Japanese Quail	84.1	[60.6–116]
Pheasant	35.4	[25.5–49.0]
Chukar	240	[110–521]
Rock Dove	50.1	[16.7–150]

TABLE I.—SENSITIVITY OF SPECIES BASED ON LD_{50} Data—Continued

Chemical and Species	LD_{50} (mg/kg)	[95% Confidence Interval]
House Sparrow	35.4	[8.85–141
2,3,7,8-TCDD:		
Guinea Pig	0.6–2 µg/kg	
Rat	22–45 µg/kg	
Rhesus Monkey	<70 µg/kg	
Dog	100–200 µg/kg	
Mouse	114–284 µg/kg	
Rabbit	115 µg/kg	
Hamster	1,157–5,051 µg/kg	
Toxaphene:		
Fulvous Whistling Duck	99.0	[37.2–264]
Mallard Duckling	30.8	[23.3–40.6]
Mallard	70.7	[37.6–133]
Sharp Tailed Grouse	19.9	[14.1–28.2]
Bobwhite	85.5	[59.3–123]
California Quail	23.7	[11.9–47.4]
Pheasant	40.0	[20.0–80.0]
Gray Partridge	23.7	[20.0–28.3]
Sandhill Crane	100–316	
Horned Lark	581	[425–794]
Mule Deer	139–240	
Domestic Goat	>160	

Adopted from Eisler 1986a,b and Hudson, et al. 1984.

TABLE II.—TOXICITY OF ORGANOMERCURY COMPOUNDS TO SELECTED MAMMALIAN SPECIES

Species	Dose (mg/kg)	Effect
Dog	0.1–0.25	Stillbirths.
Cat	0.25	Death.
Pig	0.5	Stillbirths.
Rhesus Monkey	0.5	Maternal Toxicity.
Mink	1.0	Death.
River Otter	>2.0	Death.

Adopted from Eisler 1987.

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List of Subjects

40 CFR Part 122

Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 123

Administrative practice and procedure, Confidential business information, Great Lakes, Hazardous substances, Indians-lands, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 131

Great Lakes, Reporting and recordkeeping requirements, Water pollution control.

40 CFR Part 132

Administrative practice and procedure, Great Lakes, Indians-lands, Intergovernmental relations, Reporting and recordkeeping requirements, Water pollution control.

Dated: March 30, 1993.

Carol M. Browner,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR parts 122, 123, and 131, and add part 132 as follows:

PART 122—EPA ADMINISTERED PERMIT PROGRAMS: THE NATIONAL POLLUTANT DISCHARGE ELIMINATION SYSTEM

1. The authority citation for part 122 continues to read as follows:

Authority: The Clean Water Act, 33 U.S.C. 1251 *et seq.*

2. Section 122.44 is amended by adding a new paragraph (r) to read as follows:

§ 122.44 Establishing limitations, standards, and other permit conditions (applicable to State NPDES programs, see § 123.25).

* * * * *

(r) *Great Lakes.* When a permit is issued to a facility that discharges into the Great Lakes System (as defined in 40 CFR 132.2), all conditions required by 40 CFR part 132.

PART 123—STATE PROGRAM REQUIREMENTS

3. The authority citation for part 123 continues to read as follows:

Authority: Clean Water Act, 33 U.S.C. 1251 *et seq.*

4. Section 123.25 is amended by removing "and" at the end of paragraph (a)(36), removing the period at the end of paragraph (a)(37) and adding "; and" in its place, and adding a new paragraph (a)(38) to read as follows:

§ 123.25 Requirements for permitting.

(a) * * *

(38) For a Great Lakes State or Tribe (as defined in 40 CFR 132.2), 40 CFR part 132 (NPDES permitting implementation procedures only).

* * * * *

5. Section 123.44 is amended by adding a new paragraph (c)(9) to read as follows:

§ 123.44 EPA review of and objections to State permits.

* * * * *

(c) * * *

(9) For a permit issued by a Great Lakes State or Tribe (as defined in 40 CFR 132.2), the permit does not satisfy the conditions of 40 CFR part 132.

* * * * *

6. Section 123.62 is amended by adding a new paragraph (f) to read as follows:

§ 123.62 Procedures for revision of State programs.

* * * * *

(f) Revision of a State program by a Great Lakes State or Tribe (as defined in 40 CFR 132.2) to conform to section 118 of the CWA and 40 CFR part 132 shall be accomplished as required by 40 CFR part 132.

7. Section 123.63 is amended by adding a new paragraph (a)(6) and adding and reserving paragraph (b) to read as follows:

§ 123.63 Criteria for withdrawal of State programs.

(a) * * *

(6) Where a Great Lakes State or Tribe (as defined in 40 CFR 132.2) fails to adopt the NPDES permitting implementation procedures in 40 CFR part 132.

(b) [Reserved]

PART 131—WATER QUALITY STANDARDS

8. The authority citation for part 131 continues to read as follows:

Authority: 33 U.S.C. 1251 *et seq.*

9. Section 131.1 is revised to read as follows:

§ 131.1 Scope.

This part describes the requirements and procedures for developing, reviewing, revising, and approving water quality standards by the States as authorized by section 303(c) of the Clean Water Act. Additional specific procedures for developing, reviewing, revising, and approving water quality standards for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the CWA and 40 CFR part 132, are provided in 40 CFR part 132. The reporting or recordkeeping (information) provisions in this part were approved by the Office of Management and Budget under 3504(b) of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (Approval number 2040–0049).

10. Section 131.5 is amended by revising paragraph (a)(5), by redesignating paragraph (b) as paragraph (c), and by adding a new paragraph (b) to read as follows:

§ 131.5 EPA Authority.

(a) * * *

(5) Whether the State submission meets the requirements included in § 131.6 of this part and, for Great Lakes States or Great Lakes Tribes (as defined in 40 CFR 132.2) to conform to section 118 of the CWA, the requirements of 40 CFR part 132.

(b) If EPA determines that the State or Tribe water quality standards are consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section, EPA approves the standards. EPA must disapprove the State's or Tribe's water quality standards and promulgate Federal standards under section 303(c)(4), and for Great Lakes States or Great Lakes Tribes under section 118(c)(2)(C) of the Act, if State or Tribal adopted standards are not consistent with the factors listed in paragraphs (a)(1) through (a)(5) of this section. EPA may also promulgate a new or revised standard when necessary to meet the requirements of the Act.

* * * * *

11. Section 131.21 is amended by revising paragraph (b) to read as follows:

§ 131.21 EPA review and approval of water quality standards.

* * * * *

(b) The Regional Administrator's approval or disapproval of a State water quality standard shall be based on the requirements of the Act as described in §§ 131.5 and 131.6, and, with respect to Great Lakes States or Tribes (as defined in 40 CFR 132.2), 40 CFR part 132.

* * * * *

12. Part 132 is proposed to be added as follows:

PART 132—WATER QUALITY GUIDANCE FOR THE GREAT LAKES SYSTEM

Sec.

132.1 Scope, purpose, and availability of documents.
132.2 Definitions.
132.3 Adoption of criteria.
132.4 State adoption and application of methodologies, policies and procedures.
132.5 Procedures for adoption and EPA review.
132.6 Application of part 132 requirements in Great Lakes States and Tribes.

Tables to Part 132

Appendix A to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Aquatic Life Criteria and Values
Appendix B to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors
Appendix C to Part 132—Great Lakes Water Quality Initiative Procedure for Development of Human Health Criteria and Values
Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria and Values
Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy
Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

Authority: 33 U.S.C. 1251 *et seq.*

§ 132.1 Scope, purpose, and availability of documents.

(a) This part constitutes the Water Quality Guidance for the Great Lakes System required by section 118(c)(2) of the Clean Water Act (33 U.S.C. 1251 *et seq.*) as amended by the Great Lakes Critical Programs Act of 1990 (Pub. L. 101–596, 104 Stat. 3000 *et seq.*). This Guidance specifies minimum water quality standards, antidegradation policies, and implementation procedures for the Great Lakes System to protect human health, aquatic life, and wildlife.

(b) Certain documents referenced in the appendixes to this part with a designation of NTIS and/or ERIC are available for a fee upon written request to the National Technical Information Center (NTIS), U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161. Alternatively, copies may be obtained for a fee upon written request to the Educational Resources Information Center/Clearinghouse for Science, Mathematics, and Environmental Education (ERIC/CSMEE), 1200 Chambers Road, Room 310, Columbus, Ohio 43212. When ordering, please include the NTIS or ERIC/CSMEE accession number.

(c) [Reserved]

[Note: The reporting or recordkeeping information provisions in this proposed rule have been submitted to the Office of Management and Budget under section 3504(b) of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* (ICR number 1639.01). When the reporting requirements have been approved by OMB, the text of this paragraph will be added in the final rule.]

§ 132.2 Definitions.

The following definitions apply in this part. Terms not defined in this section have the meaning given by the Clean Water Act or EPA implementing regulations.

Acceptable daily exposure (ADE) is an estimate of the maximum daily dose of a substance which is not expected to result in adverse effects to the general human population, including sensitive subgroups.

Acute toxic unit (TU_a) is 100/LC50 where the LC50 is expressed as a percent.

Acute toxicity is an adverse effect in an organism as a result of exposure to a toxicant for a relatively short period of time relative to the organism's natural life span.

Acute-chronic ratio (ACR) is the ratio of the acute toxicity of an effluent or a toxicant to its chronic toxicity. The ACR is used as a factor for estimating chronic toxicity on the basis of acute toxicity data, or for estimating acute toxicity on the basis of chronic toxicity data.

Adverse effect is any deleterious effect to organisms due to exposure to a substance. This includes effects which are or may become debilitating, harmful or toxic to the normal functions of the organism, but does not include non-harmful effects such as tissue discoloration alone or the induction of enzymes involved in the metabolism of the substance.

Allowable dilution flow (Q_{ad}) is the portion of the stream design flow used in developing the wasteload allocation for sources regulated by the National Pollution Discharge Elimination System (NPDES) program. The Q_{ad} is calculated in procedure B3, section D.3.a.ii, of appendix F of this part.

Bioaccumulation is the uptake and retention of a substance by an aquatic organism from its surrounding media and food.

Bioaccumulation factor (BAF) is the ratio (in L/kg) of the substance's concentration in tissue of aquatic organisms resulting from bioaccumulation, versus its concentration in ambient water.

Bioaccumulative chemical of concern (BCC) is any chemical which, upon entering the surface waters, by itself or as its toxic transformation product, bioaccumulates in aquatic organisms by a human health bioaccumulation factor greater than 1000, after considering metabolism and other physicochemical properties that might enhance or inhibit bioaccumulation, in accordance with the methodology in appendix B of this part. BCCs include, but are not limited to, the pollutants identified as BCCs in part A of Table 6 of this part.

Bioconcentration is the uptake and retention of a substance by an aquatic organism from the surrounding water only through gill membranes or other external body surfaces.

Bioconcentration factor (BCF) is the ratio of the substance's concentration in tissue of aquatic organisms resulting from bioconcentration versus its concentration in water.

Biomagnification is the transfer and step-wise increase in bioaccumulation of a chemical in organisms through successive trophic levels.

Carcinogen is a substance which causes an increased incidence of benign or malignant neoplasms, or substantially decreases the time to develop neoplasms, in animals or humans.

Chronic toxic unit (TU_c) is 100/NOEC, where the NOEC is expressed as a percent.

Chronic toxicity is an adverse effect in an organism as a result of exposure to a toxicant for a major portion of time relative to the organism's natural life span.

Compliance evaluation level (CEL) is the level at which compliance with a water quality-based effluent limitation in an NPDES permit is assessed. It is the minimum level, when the water quality-based effluent limit is less than the minimum level. Otherwise, it is the water quality-based effluent limit.

Connecting channels of the Great Lakes are the Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border.

Criterion continuous concentration (CCC) is the lower of the Final Plant Value or the Final Chronic Value. It is the highest instream concentration of a material to which aquatic organisms can be exposed indefinitely without causing unacceptable effect.

Criterion maximum concentration (CMC) is one half the FAV. It is the highest instream concentration of a material to which aquatic organisms can be exposed for a brief period of time without causing an unacceptable acute effect.

Depuration is the loss of a substance from an aquatic organism.

Detection level is the minimum concentration of an analyte (substance) that can be measured and reported with a 99 percent confidence that the analyte concentration is greater than zero as determined by the procedure set forth at appendix B of 40 CFR part 136.

Dilution fraction is the factor which, when multiplied by the stream design flow, determines the allowable dilution flow (Q_{ad}). The dilution fraction is calculated as detailed in section D.3.a.iii. of procedure B3 in appendix F of this part.

EC50 is the concentration of a test material at which 50 percent of the exposed organisms exhibit an observable adverse effect (such as death, immobilization, or serious incapacitation) during a specified time period.

Existing discharger is any source which is neither a new source as defined by 40 CFR 122.2 nor a new discharge as defined by 40 CFR 122.2.

Existing uses are those uses actually attained in the water body on or after November 28, 1975, whether or not they are included in the water quality standards.

Federal Indian Reservation, Indian Reservation, or Reservation means all land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

Final acute value (FAV) is an estimate of the concentration of a material such that 95 percent of the genera (with which acceptable acute toxicity tests have been conducted on the material) have higher acute toxicity values. The calculated FAV may be lowered to be equal to the Species Mean Acute Value of a commercially or recreationally important species of the Great Lakes System.

Final chronic value (FCV) is an estimate of the concentration of a material such that 95 percent of the genera (with which acceptable chronic toxicity tests have been conducted on the material) have higher chronic toxicity values. Alternatively, the FCV may be determined by dividing the FAV by an acute-chronic ratio. The calculated FCV may be lowered to be equal to the Species Mean Chronic Value of a commercially or recreationally important species of the Great Lakes System.

Final plant value (FPV) is the result of a 96-hour test conducted with an alga or chronic test conducted with an aquatic vascular plant.

Genus mean acute value (GMAV) is the geometric mean of the Species Mean Acute Values for the genus.

Genus mean chronic value (GMCV) is the geometric mean of the Species Mean Chronic Values for the genus.

Great Lakes means Lake Ontario, Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, and Lake Superior; and the connecting channels (Saint Mary's River, Saint Clair River, Detroit River, Niagara River, and Saint Lawrence River to the Canadian Border).

Great Lakes States and Great Lakes Tribes, or Great Lakes States and Tribes means the States of Illinois, Indiana, Michigan, Minnesota, New York, Ohio, Pennsylvania, and Wisconsin, and any Indian tribe as defined in this part which is located in whole or in part within the drainage basin of the Great Lakes, and that EPA has determined qualifies under section 518 of the Clean Water Act to administer programs under sections 303 (see 40 CFR 131.8) and/or 402 of the Clean Water Act.

Great Lakes System means all the streams, rivers, lakes and other bodies of water within the drainage basin of the Great Lakes.

Human cancer criterion (HCC) is a Human Cancer Value (HCV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human cancer value (HCV) is the maximum ambient water concentration of a substance at or below which a lifetime of exposure from either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water related recreation activities, will represent a plausible upper bound risk of contracting cancer of one in 100,000 using the exposure assumptions specified in the methodologies for the development of Human Health Criteria and Values in appendix C of this part.

Human noncancer criterion (HNC) is a Human Noncancer Value (HNV) for a pollutant that meets the minimum data requirements for Tier I specified in appendix C of this part.

Human noncancer value (HNV) is the maximum ambient water concentration of a substance at or below which adverse noncancer effects are not likely to occur in the human population from lifetime exposure via either: drinking the water, consuming fish from the water, and water-related recreation activities; or consuming fish from the water, and water-related recreation activities using the Human Health Criteria and Values in appendix C of this part.

Indian Tribe or *Tribe* means any Indian Tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a Federal Indian reservation.

LC50 is the concentration of a test material at which 50 percent of the exposed organisms die during a specified time period.

Linear multi-stage model is a conservative mathematical model for cancer risk assessment. This model fits linear dose-response curves to low doses. It is consistent with a no-threshold model of carcinogenesis, i.e., exposure to even a very small amount of the substance produces a finite increased risk of cancer.

Load allocation (LA) is the portion of a receiving water's loading capacity that is attributed either to one of its existing or future non-point sources or to natural background sources, as more fully defined at 40 CFR 130.2(g). Nonpoint sources include: in-place contaminants, direct wet and dry deposition, groundwater inflow, and overland runoff.

Loading capacity is the greatest amount of loading that a water can receive without violating water quality standards.

Lowest observed adverse effect level (LOAEL) is the lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

Minimum level (ML) is the level at which the analytical system gives recognizable spectra and acceptable calibration points. It is based upon interlaboratory analyses for the analyte in the matrix of concern.

No observed adverse effect level (NOAEL) is the highest tested dose or concentration of a substance which resulted in no observed adverse effect in exposed test organisms when all lower levels resulted in no observed adverse effect.

No observed effect concentration (NOEC) is the highest tested concentration of an effluent or a

toxicant at which no adverse effects are observed on the aquatic test organisms, at a specific time of observation, when all lower levels resulted in no observed effect.

Noncarcinogen is a substance which is not classified as a known, probable, or possible human carcinogen according to the weight-of-evidence assessment.

Octanol/water partition coefficient (K_{ow}) is the ratio, at equilibrium, of the concentration of a substance in the octanol phase to its concentration in the aqueous phase in a two-phase octanol/water system.

Open waters of the Great Lakes means all of the waters within Lake Erie, Lake Huron (including Lake St. Clair), Lake Michigan, Lake Ontario, and Lake Superior lakeward from a line drawn across the mouth of tributaries to the Lakes, including all waters enclosed by constructed breakwaters, but not including the connecting channels.

Quantification level is a measurement of the concentration of a chemical obtained by using a specified laboratory procedure, at a specified concentration above the detection level. It is considered the lowest concentration at which a particular substance can be quantitatively measured using a specified laboratory procedure.

Quantitative structure activity relationship (QSAR) or structure activity relationship (SAR) is a mathematical relationship between a property (activity) of a chemical and a number of descriptors of the chemical. These descriptors are chemical or physical characteristics obtained experimentally or from the structure of the chemical.

Reasonable potential is where an effluent is projected or calculated to cause or contribute to an excursion above any water quality standard, including State narrative criteria for water, by using procedures which at a minimum account for existing controls on point and nonpoint sources of pollution, the variability of the pollutant or pollutant parameter in the effluent, the sensitivity of the species to toxicity testing (when evaluating whole effluent toxicity), and where appropriate the dilution of the effluent in the receiving water.

Relative source contribution (RSC) is the factor (percentage) used in calculating a HNV or HNC to account for all sources of exposure to a contaminant. The RSC reflects the percent of total exposure which can be attributed to surface water through water intake and fish consumption.

Risk associated dose (RAD) is a dose of a known or presumed carcinogenic substance in milligrams/kilogram/day which, over a lifetime of exposure, is calculated to be associated with a plausible upper bound incremental cancer risk equal to one in 100,000.

Slope factor, also known as q_1^*, is the incremental rate of cancer development calculated through use of a linear multistage model. It is expressed in (mg/kg)/day of exposure to the chemical in question.

Species mean acute value (SMAV) is the geometric mean of the results of all flow-through acute toxicity tests (LC50) in which the concentrations of test material were measured. For a species for which no such result is available, the SMAV should be calculated as the geometric mean of all available acute values.

Species mean chronic value (SMCV) is the geometric mean of the results of all flow-through chronic toxicity tests in which the concentrations of test material were measured. For a species for which no such result is available, the SMCV should be calculated as the geometric mean of all available chronic values.

Steady-state BAF/BCF is a BAF or BCF that does not change substantially over time. It is the BAF or BCF that exists when uptake and depuration are equal.

Stream design flow is the stream flow that represents critical conditions, upstream of the source, for protection of aquatic life, human health, and wildlife.

Superlipophilic chemicals are chemicals with a very strong affinity for lipids, having a log K_{ow} greater than 6.5.

Threatened or endangered species are those species that are listed as threatened or endangered under the Federal Endangered Species Act.

Threshold effect is an effect of a substance for which there is a theoretical or empirically established dose or concentration below which the effect does not occur.

Tier I criteria are numeric values derived by use of the Tier I methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that either have been adopted as numeric criteria into a water quality standard or are used to implement narrative water quality criteria.

Tier II values are numeric values derived by use of the Tier II methodologies in appendixes A, C and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part, that are used to implement narrative water quality criteria.

Total maximum daily load (TMDL) is the sum of the individual wasteload allocations for point sources and load allocations for nonpoint sources and natural background, as more fully defined at 40 CFR 130.2(i). A TMDL sets and allocates the maximum amount of a pollutant which may be introduced into a water body and still assure attainment and maintenance of water quality standards.

Tributaries of the Great Lakes System means all waters of the Great Lakes System that are not open waters of the Great Lakes, or connecting channels.

Uncertainty factor (UF) is one of several, generally 10-fold, factors used in operationally deriving criteria from experimental data.

Uptake is the sorption of a substance into or onto an aquatic organism.

Wasteload allocation (WLA) is the portion of a receiving water's loading capacity that is allocated to one of its existing or future point sources of pollution, as more fully defined at 40 CFR 130.2(h).

Wet weather point source is a point source which is either an outfall from a municipal separate storm sewer as defined at 40 CFR 122.26(b)(8), a storm water discharge associated with industrial activity as defined at 40 CFR 122.26(b)(14), or a combined sewer overflow. A combined sewer overflow is a flow from a combined sewer in excess of the interceptor or regulator capacity which is discharged into a receiving water body without going to a publicly owned treatment works. Combined sewer overflows occur prior to the headworks of a treatment facility. A storm water discharge associated with industrial activity which is mixed with process wastewater shall not be considered a wet-weather point source.

§ 132.3 Adoption of criteria.

The Great Lakes States and Tribes shall adopt numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act applicable to waters of the Great Lakes System in accordance with § 132.4(d) that are equal to or more restrictive than:

(a) The acute water quality criteria for protection of aquatic life in Table 1 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(b) The chronic water quality criteria for protection of aquatic life in Table 2 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part;

(c) The water quality criteria for protection of human health in Table 3 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part; and

(d) The water quality criteria for protection of wildlife in Table 4 of this part, or a site-specific modification thereof in accordance with procedure 1 of appendix F of this part.

§ 132.4 State adoption and application of methodologies, policies and procedures.

(a) The Great Lakes States and Tribes shall adopt requirements applicable to waters of the Great Lakes System for the purposes of sections 118, 303, and 402 of the Clean Water Act that are consistent with:

(1) The definitions in § 132.2;

(2) The Methodologies for Development of Aquatic Life Criteria and Values in appendix A of this part;

(3) The Methodology for Development of Bioaccumulation Factors in appendix B of this part;

(4) The Methodologies for Development of Human Health Criteria and Values in appendix C of this part;

(5) The Methodologies for Development of Wildlife Criteria and Values in appendix D of this part;

(6) The Antidegradation Policy in appendix E of this part; and

(7) The Implementation Procedures in appendix F of this part.

(b) Except as provided in paragraphs (g) and (h) of this section, the Great Lakes States and Tribes shall use the methodologies designated as Tier I methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part when adopting or revising numeric water quality criteria for the purposes of section 303(c) of the Clean Water Act for the Great Lakes System.

(c) Except as provided in paragraphs (g) and (h) of this section, the Great Lakes States and Tribes shall apply the methodologies designated as Tier I and Tier II methodologies in appendixes A, C, and D of this part, the methodology in appendix B of this part, and the procedures in appendix F of this part to develop numeric values when implementing narrative water quality criteria adopted for purposes of section 303(c) of the Clean Water Act.

(d) The water quality criteria and values adopted or developed pursuant to paragraphs (a) through (c) of this section shall apply as follows:

(1) The acute water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(2) The chronic water quality criteria and values for the protection of aquatic life, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(3) The water quality criteria and values for protection of human health, or site-specific modifications thereof, shall apply as follows:

(i) Criteria and values derived as HCV-Drinking and HNV-Drinking shall apply to the Open Waters of the Great Lakes, all connecting channels of the Great Lakes, and all other waters of the Great Lakes System that have been designated as public water supplies by any State or Tribe in accordance with 40 CFR 131.10.

(ii) Criteria and values derived as HCV-Nondrinking and HNV-Nondrinking shall apply to all waters of the Great Lakes System other than those in paragraph (d)(3)(i) of this section.

(4) Criteria and values for protection of wildlife, or site-specific modifications thereof, shall apply to all waters of the Great Lakes System.

(e) The Great Lakes States and Tribes shall apply the implementation procedures adopted pursuant to § 132.4(a)(7) for all applicable purposes under the Clean Water Act, including developing total maximum daily loads for the purposes of section 303(d) and water quality-based effluent limits for the purposes of section 402, in establishing controls on the discharge of any pollutant to the Great Lakes System by any point source with the following exceptions:

(1) The Great Lakes States and Tribes are not required to apply these implementation procedures in establishing controls on the discharge of any pollutant by a wet weather point source. Any adopted implementation procedures shall conform with all applicable Federal, State and Tribal requirements.

(2) The Great Lakes States and Tribes may, but are not required to, apply procedures 1, 2, 3, 4, 5, 7, 8, and 9 of appendix F of this part in establishing controls on the discharge of any pollutant set forth in Table 5 of this part. Any procedures applied in lieu of these implementation procedures shall conform with all applicable Federal, State, and Tribal requirements.

(f) The Great Lakes States and Tribes shall apply the antidegradation policy adopted pursuant to § 132.4(a)(6) for all applicable purposes under the Clean Water Act, including 40 CFR 131.12, for all pollutants.

(g) For pollutants listed in Table 5 of this part, or for any pollutant other than those in Table 5 of this part for which the State or Tribe demonstrates that one or more methodologies or procedures in this part are not scientifically defensible, the Great Lakes States and Tribes shall:

(1) Apply any methodologies and procedures acceptable under 40 CFR part 131 when developing water quality criteria or implementing narrative criteria; and

(2) Apply the implementation procedures in appendix F of this part or alternative procedures consistent with all applicable Federal, State, and Tribal laws.

(h) Nothing in this part shall prohibit the Great Lakes States and Tribes from adopting numeric water quality criteria, narrative criteria, or water quality values that are more stringent than criteria or values that would be derived from application of the methodologies set forth in appendixes A, B, C, and D of this part or to adopt antidegradation policies and implementation procedures more stringent than those set forth in appendixes E and F of this part.

§ 132.5 Procedures for adoption and EPA review.

(a) The Great Lakes States and Tribes shall adopt and submit for EPA review and approval the criteria, methodologies, policies, and procedures developed pursuant to this part no later than eighteen months from the date of final publication of this part.

(b) The following elements must be included in each submission to EPA for review:

(1) The criteria, methodologies, policies, and procedures developed pursuant to this part;

(2) Certification by the Attorney General or other appropriate legal authority pursuant to 40 CFR 123.62 and 40 CFR 131.6(e) as appropriate;

(3) All other information required for submission of NPDES program modifications under 40 CFR 123.62; and

(4) General information which will aid EPA in determining whether the criteria, methodologies, policies and procedures are consistent with the requirements of the Clean Water Act and this part, as well as information on general policies which may affect their application and implementation.

(c) If a Great Lakes State or Tribe fails to submit any criteria, methodologies, policies, and procedures pursuant to this part to EPA for review, the requirements of this part shall apply to discharges within the State or Federal Indian Reservation upon EPA's publication of a final rule indicating the effective date of the part 132 requirements in the identified jurisdictions.

(d) If a Great Lakes State or Tribe submits criteria, methodologies, policies, and procedures pursuant to this part to EPA for review, EPA shall issue public notice and provide a

minimum of 30 days for public comment on all received State or Tribal submissions. The public notice shall conform with the requirements of 40 CFR 123.62. Following the public comment period, EPA shall either:

(1) Publish notice of approval of the submission in the **Federal Register** within 60 days of such submission; or

(2) Notify the State or Tribe within 90 days of such submission that EPA has determined that all or part of the submission is inconsistent with the requirements of the Clean Water Act or this part and identify any necessary changes to obtain EPA approval. If the State or Tribe fails to adopt such changes within 90 days after the notification, EPA shall publish a notice in the **Federal Register** identifying the approved and disapproved elements of the submission and a final rule in the **Federal Register** identifying the provisions of part 132 that shall apply to discharges within the State or Federal Indian Reservation.

(e) EPA's approval or disapproval of a State or Tribal submission shall be based on the requirements of this part and of the Clean Water Act. EPA will determine that the criteria, methodologies, policies, and procedures in a State or Tribal submission are consistent with the requirements of this part if:

(1) *For pollutants listed in Tables 1, 2, 3, and 4 of this part.* The Great Lakes State or Tribe has adopted numeric water quality criteria equal to or more restrictive than each of the numeric criteria in Tables 1, 2, 3, and 4 of this part, taking into account any site-specific criteria modifications in accordance with procedure 1 of appendix F of this part;

(2) *For pollutants other than those listed in Tables 1, 2, 3, and 4 of this part.* The Great Lakes State or Tribe demonstrates that either:

(i) It has adopted numeric criteria in its water quality standards that were derived, or are equal to or more restrictive than could be derived, using the methodologies in appendixes A, B, C, and D of this part, and the site-specific criteria modification procedures of appendix F of this part; or

(ii) It has adopted a procedure by which water quality-based effluent limits and total maximum daily loads are developed using the more restrictive of:

(A) Numeric criteria adopted by the State into State water quality standards prior to the date of final publication of this part; or

(B) Water quality criteria and values derived pursuant to § 132.4(c); and

(3) *For methodologies, policies, and procedures.* The Great Lakes State or Tribe has adopted methodologies, policies, and procedures equal to or more restrictive than the corresponding methodology, policy, or procedure in § 132.4. The Great Lakes State or Tribe may adopt provisions which are more restrictive than those contained in this part; however, a more restrictive individual provision is not justification for adoption of a less restrictive requirement for a separate element of this part.

(f) EPA's approval of the elements of a State's or Tribe's submission will constitute approval under section 118 of the Clean Water Act, approval of the submitted water quality standards pursuant to section 303 of the Clean Water Act, and approval of the submitted modifications to the State's or Tribe's NPDES program pursuant to section 402 of the Clean Water Act.

§ 132.6 Application of part 132 requirements in Great Lakes States and Tribes [Reserved]

[Note: The text of this section is reserved. Text will be added as necessary through subsequent rulemaking in accordance with § 132.5.]

Tables to Part 132

TABLE 1.—ACUTE WATER QUALITY CRITERIA FOR PROTECTION OF AQUATIC LIFE IN AMBIENT WATER

Chemical	CMC (µg/L)
Arsenic (III)	340
Cadmium	[1] 2.1
Chromium (III)	[1] 1000
Chromium (VI)	16
Copper	[1] 7.3
Cyanide, free	22
Dieldrin	0.24
Endrin	0.09
Lindane	0.95
Mercury (II)	0.83
Nickel	[1] 260
Parathion	.065
Pentachlorophenol	[2] 5.3
Phenol	3700
Total Selenium	20
Zinc	[1] 67

[1] The toxicity of this chemical is hardness related; the criterion expressed is at a hardness of 50 mg/L.

[2] The criterion for this chemical is pH dependent; the criterion expressed is at a pH of 6.5.

TABLE 2.—CHRONIC WATER QUALITY CRITERIA FOR PROTECTION OF AQUATIC LIFE IN AMBIENT WATER

Chemical	CCC (µg/L)
Arsenic (III)	150
Cadmium	[1] 0.78
Chromium (III)	[1] 49
Chromium (VI)	11
Copper	[1] 5.2
Cyanide, free	5.2
Dieldrin	0.056
Endrin	0.037
Mercury (II)	0.44
Nickel	[1] 29
Parathion	0.013
Pentachlorophenol	[2] 3.3
Phenol	120
Total Selenium	5.0
Zinc	[1] 60

[1] The toxicity of this chemical is hardness related; the criterion expressed is at a hardness of 50 mg/L.

[2] The toxicity of this chemical is pH related; the criterion expressed is at a pH of 6.5.

TABLE 3.—WATER QUALITY CRITERIA FOR PROTECTION OF HUMAN HEALTH

Chemical	HNV (ng/L)		HCV (ng/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Benzene	2.E4	2.E5	1.E4	1.E5
Chlordane	9	D	0.2	0.2
Chlorobenzene	5.E5	1.8E6	.....	.....
Cyanides	6.E5	6.E7	.....	.....
DDT	1.0	1.0	0.07	0.07
Dieldrin	7	7	0.1	0.1
2,4-Dimethylphenol	3.E5	5.E5	.....	.....
2,4-Dinitrophenol	7.E4	1.7E6	.....	.....
Heptachlor	300	300	0.5	0.5

TABLE 3.—WATER QUALITY CRITERIA FOR PROTECTION OF HUMAN HEALTH—Continued

Chemical	HNV (ng/L)		HCV (ng/L)	
	Drinking	Nondrinking	Drinking	Nondrinking
Hexachlorobenzene	10	10	0.1	0.1
Hexachloroethane	2.E3	3.E3	3.E3	4.E3
Lindane	700	800	.....	.....
Mercury[1]	2	2	.....	.....
Methylene chloride	2.E6	9.6E7	5.E4	2.E6
PCBs (class)	.....	.....	3.E–3	3.E–3
Pentachlorophenol	2.E5	2.E5	500	500
2,3,7,8-TCDD	1.E–4	1.E–4	1.E–5	1.E–5
Toluene	6.E6	2.6E7	.....	.....
Toxaphene	5	6	0.02	0.02
Trichloroethylene	6.E5	5.E6	3.E4	2.E5

[1] Includes Methylmercury.

TABLE 4.—WATER QUALITY CRITERIA FOR PROTECTION OF WILDLIFE

Chemical	Criteria (pg/L)
DDT and Metabolites	0.87
Mercury (including Methylmercury)	180
Polychlorinated biphenyls (PCBs)	17
2,3,7,8-TCDD	0.0096

Table 5. Excluded pollutants

Alkalinity
Ammonia
Bacteria
Biochemical oxygen demand (BOD)
Chlorine
Color
Dissolved oxygen
Dissolved solids
Hydrogen sulfide
pH
Phosphorus
Salinity
Sulfide
Temperature
Total and suspended solids
Turbidity

Table 6. Pollutants of Initial Focus in the Great Lakes Water Quality Initiative

A. Pollutants that are bioaccumulative chemicals of concern (BCCs):

Aldrin
4-Bromophenyl phenyl ether
Chlordane
4,4-DDD; p,p-DDD; 4,4-TDE; p,p-TDE
4,4-DDE; p,p-DDE
4,4-DDT; p,p-DDT
Dieldrin
Endrin
Heptachlor
Heptachlor epoxide
Hexachlorobenzene
Hexachlorobutadiene; hexachloro-1,3-butadiene
Hexachlorocyclohexane; BHC
alpha-Hexachlorocyclohexane; alpha-BHC
beta-Hexachlorocyclohexane; beta-BHC
delta-Hexachlorocyclohexane; delta-BHC
Lindane; gamma-BHC; gamma-hexachlorocyclohexane
Mercury
Methoxychlor
Mirex; dechlorane
Octachlorostyrene
PCBs; polychlorinated biphenyls
Pentachlorobenzene
Photomirex
2,3,7,8-TCDD; dioxin
1,2,3,4-Tetrachlorobenzene
1,2,4,5-Tetrachlorobenzene
Toxaphene

B. Pollutants that are potential bioaccumulative chemicals of concern:

Benzo[a]pyrene; 3,4-benzopyrene
3,4-Benzofluoranthene; benzo[b]fluoranthene
11,12-Benzofluoranthene; benzo[k]fluoranthene
1,12-Benzoperylene; benzo[ghi]perylene
4-Chlorophenyl phenyl ether
1,2:5,6-Dibenzanthracene; dibenz[a,h]anthracene
Dibutyl phthalate; di-n-butyl phthalate
Indeno[1,2,3-cd]pyrene; 2,3-o-phenylene pyrene
Phenol
Toluene; methylbenzene

C. Pollutants that are neither bioaccumulative chemicals of concern nor potential bioaccumulative chemicals of concern:

Acenaphthene
Acenaphthylene
Acrolein; 2-propenal
Acrylonitrile
Aluminum
Anthracene
Antimony
Arsenic
Asbestos
1,2-Benzanthracene; benz[a]anthracene
Benzene
Benzidine
Beryllium
Bis(2-chloroethoxy)methane
Bis(2-chloroethyl) ether
Bis(2-chloroisopropyl) ether
Bromoform; tribromomethane
Butyl benzyl phthalate
Cadmium
Carbon tetrachloride; tetrachloromethane
Chlorobenzene
p-Chloro-m-cresol; 4-chloro-3-methylphenol
Chlorodibromomethane
Chloroethane
2-Chloroethyl vinyl ether
Chloroform; trichloromethane
2-Chloronaphthalene
2-Chlorophenol
Chlorpyrifos
Chromium
Chrysene
Copper
Cyanide
2,4-D; 2,4-Dichlorophenoxyacetic acid
DEHP; di(2-ethylhexyl) phthalate
Diazinon
1,2-Dichlorobenzene
1,3-Dichlorobenzene
1,4-Dichlorobenzene
3,3-Dichlorobenzidine
Dichlorobromomethane; bromodichloromethane
1,1-Dichloroethane
1,2-Dichloroethane; vinylidene chloride
1,1-Dichloroethylene
1,2-trans-Dichloroethylene
2,4-Dichlorophenol
1,2-Dichloropropane
1,3-Dichloropropene; 1,3-dichloropropylene
Diethyl phthalate
2,4-Dimethylphenol; 2,4-xylenol
Dimethyl phthalate
4,6-Dinitro-o-cresol; 2-methyl-4,6-dinitrophenol
2,4-Dinitrophenol
2,4-Dinitrotoluene
2,6-Dinitrotoluene
Dioctyl phthalate; di-n-octyl phthalate
1,2-Diphenylhydrazine
Endosulfan; thiodan
alpha-Endosulfan

beta-Endosulfan
Endosulfan sulfate
Endrin aldehyde
Ethylbenzene
Fluoranthene
Fluorene; 9H-fluorene
Fluoride
Guthion
Hexachlorocyclopentadiene
Hexachloroethane
Iron
Isophorone
Lead
Malathion
Methyl bromide; bromomethane
Methyl chloride; chloromethane
Methylene chloride; dichloromethane
Naphthalene
Nickel
Nitrobenzene
2-Nitrophenol
4-Nitrophenol
N-Nitrosodimethylamine
N-Nitrosodiphenylamine
N-Nitrosodipropylamine; N-nitrosodi-n-propylamine
Parathion
Pentachlorophenol
Phenanthrene
Pyrene
Selenium
Silver
1,1,2,2-Tetrachloroethane
Tetrachloroethylene
Thallium
1,2,4-Trichlorobenzene
1,1,1-Trichloroethane
1,1,2-Trichloroethane
Trichloroethylene; trichloroethene
2,4,6-Trichlorophenol
Vinyl chloride; chloroethylene; chloroethene
Zinc

Appendix A to Part 132—Great Lakes Water Quality Initiative Methodologies for Development of Aquatic Life Criteria and Values

Methodology for Deriving Aquatic Life Criteria: Tier I

I. Definitions

A. *Material of Concern.* 1. Each separate chemical that does not ionize substantially in most natural bodies of water should usually be considered a separate material, except possibly for structurally similar organic compounds that only exist in large quantities as commercial mixtures of the various compounds and apparently have similar biological, chemical, physical, and toxicological properties.

2. For chemicals that ionize substantially in most natural bodies of water (e.g. some phenols and organic acids, some salts of phenols and organic acids, and most inorganic salts and coordination complexes of metals and metalloids), all forms that would be in chemical equilibrium should usually be considered one material. Each different oxidation state of a metal and each different non-ionizable covalently bonded organometallic compound should usually be considered a separate material.

3. The definition of the material should include an operational analytical component. Identification of a material simply as "sodium," for example, implies "total sodium", but leaves room for doubt. If "total" is meant, it must be explicitly stated. Even "total" has different operational definitions, some of which do not necessarily measure "all that is there" in all samples. Thus, it is also necessary to reference or describe the analytical method that is intended. The selection of the operational analytical component should take into account the analytical and environmental chemistry of the material, the desirability of using the same analytical method on samples from laboratory tests, ambient water, and aqueous effluents, and various practical considerations, such as labor and equipment requirements, and whether the method would require measurement in the field or would allow measurement after samples are transported to a laboratory.

The primary requirements of the operational analytical component are that it be appropriate for use on samples of receiving water, that it be compatible with the available toxicity and bioaccumulation data without making extrapolations that are too hypothetical, and that it rarely result in underprotection or overprotection of aquatic organisms and their uses.

Because an ideal analytical measurement will rarely be available, a compromise measurement will usually have to be used. This compromise measurement must fit with the general approach that if an ambient concentration is lower than the criterion, unacceptable effects will probably not occur, i.e., the compromise measure must not err on the side of underprotection when measurements are made on a surface water. Because the chemical and physical properties of an effluent are usually quite different from those of the receiving water, an analytical method that is acceptable for analyzing an effluent might not be appropriate for analyzing a receiving water, and vice versa. If the ambient concentration calculated from a measured concentration in an effluent is higher then the criterion, an additional option is to measure the concentration after dilution of the effluent with the receiving water to determine if the measured concentration is lowered by such phenomena as complexation or sorption. A further option, of course, is to derive a site-specific criterion. Thus, the criterion should be based on an appropriate analytical measurement, but the criterion is not rendered useless if an ideal measurement either is not available or is not feasible.

Note: The analytical chemistry of the material might have to be taken into account when defining the material or when judging the acceptability of some toxicity tests, but a criterion must not be based on the sensitivity of an analytical method. When aquatic organisms are more sensitive than routine analytical methods, the proper solution is to develop better analytical methods, not to underprotect aquatic life.

B. *Acute Toxicity.* An adverse effect (usually lethality) in an aquatic organism as a result of exposure to a toxicant for a relatively short period (i.e., 24 to 96 hours) of time relative to the organism's natural life span.

C. *Chronic Toxicity.* An adverse effect (i.e., reduced growth, reproductive effects, etc., in addition to lethality) in an aquatic organism as a result of exposure to a toxicant for a significant portion of time relative to the organism's natural life span.

II. Collection of Data

A. Collect all data available on the material concerning toxicity to aquatic animals and plants.

B. All data that are used should be available in typed, dated, and signed hard copy (publication, manuscript, letter, memorandum, etc.) with enough supporting information to indicate that acceptable test procedures were used and that the results are probably reliable. In some cases, it may be appropriate to obtain written information from the investigator, if possible. Information that is not available for distribution shall not be used.

C. Questionable data, whether published or unpublished, must not be used. For example, data must be rejected if they are from tests that did not contain a control treatment, tests in which too many organisms in the control treatment died or showed signs of stress or disease, and tests in which distilled or deionized water was used as the dilution water without the addition of appropriate salts.

D. Data on technical grade materials may be used if appropriate, but data on formulated mixtures and emulsifiable concentrates of the material must not be used.

E. For some highly volatile, hydrolyzable, or degradable materials, it is probably appropriate to use only results of flow-through tests in which the concentrations of test material in test solutions were measured using acceptable analytical methods.

F. Data must be rejected if obtained using:

1. Brine shrimp, because they usually only occur naturally in water with salinity greater than 35g/kg.

2. Species that do not have reproducing wild populations in North America.

3. Organisms that were previously exposed to substantial concentrations of the test material or other contaminants.

4. Saltwater species except for use in deriving acute-chronic ratios.

G. Questionable data, data on formulated mixtures and emulsifiable concentrates, and data obtained with non-resident species or previously exposed organisms may be used to provide auxiliary information but shall not be used in the derivation of criteria.

III. Required Data

A. Certain data should be available to help ensure that each of the major kinds of possible adverse effects receives adequate consideration. Results of acute and chronic toxicity tests with representative species of aquatic animals are necessary so that data available for tested species can be considered a useful indication of the sensitivities of appropriate untested species. Fewer data concerning toxicity to aquatic plants are required because procedures for conducting

tests with plants and interpreting the results of such tests are not as well developed.

B. To derive a Great Lakes Tier I criterion for freshwater aquatic organisms and their uses, the following must be available:

1. Results of acceptable acute tests (see section IV of this appendix) with at least one species of freshwater animal in at least eight different families such that all of the following are included:

a. The family Salmonidae in the class Osteichthyes;

b. One other family (preferably a commercially, or recreationally important, warmwater species) in the class Osteichthyes (e.g., bluegill, channel catfish, etc.);

c. A third family in the phylum Chordata (e.g., fish, amphibian, etc.);

d. A planktonic crustacean (e.g., a cladoceran, copepod, etc.);

e. A benthic crustacean (e.g., ostracod, isopod, amphipod, crayfish, etc.);

f. An insect (e.g., mayfly, dragonfly, damselfly, stonefly, caddisfly, mosquito, midge, etc.);

g. A family in a phylum other than Arthropoda or Chordata (e.g., Rotifera, Annelida, Mollusca, etc.);

h. A family in any order of insect or any phylum not already represented.

2. Acute-chronic ratios (see section VI of this appendix) with a species of aquatic animal in at least three different families provided that of the three species:

a. At least one is a fish;

b. At least one is an invertebrate; and

c. At least one species is an acutely sensitive freshwater species (the other two may be saltwater species).

3. Results of at least one acceptable test with a freshwater algae or vascular plant is desirable but not required for criterion derivation (see section VIII of this appendix). If plants are among the aquatic organisms most sensitive to the material, results of a test with a plant in another phylum (division) should also be available.

C. If all required data are available, a numerical criterion can usually be derived, except in some cases. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix) more data will be required.

Similarly, if all required data are not available, a numeric criterion should not be derived except in special cases. For example, derivation of a criterion might not be possible if the available acute-chronic ratios vary by more than a factor of ten with no apparent pattern. Also, if a criterion is to be related to a water quality characteristic (see sections V and VII of this appendix) more data will be required.

Similarly, if all required data are not available, a numeric criterion should not be derived except in special cases.

D. Confidence in a criterion usually increases as the amount of available pertinent information increases. Thus, additional data are usually desirable.

IV. Final Acute Value

A. Appropriate measures of the acute (short-term) toxicity of the material to a variety of species of aquatic animals are used to calculate the Final Acute Value. The Final Acute Value is an estimate of the concentration of the material corresponding to a cumulative probability of 0.05 in the acute toxicity values for the genera with which acceptable acute tests have been conducted on the material. However, in some cases, if the Species Mean Acute Value of a commercially or recreationally important species of the Great Lakes System is lower than that calculated Final Acute Value, then the Species Mean Acute Value replaces the calculated Final Acute Value in order to provide protection for that important species.

B. Acute toxicity tests shall be conducted using acceptable procedures.

C. Except for results with saltwater annelids and mysids, results of acute tests during which the test organisms were fed shall not be used, unless data indicate that the food did not affect the toxicity of the test material.

D. Results of acute tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, should not be used, unless a relationship is developed between acute toxicity and organic carbon or particulate matter, or unless data show that organic carbon or particulate matter, etc., do not affect toxicity.

E. Acute values must be based upon endpoints which reflect the total severe adverse impact of the test material on the organisms used in the test. Therefore, only the following kinds of data on acute toxicity to aquatic animals shall be used:

1. Tests with daphnids and other cladocerans must be started with organisms less than 24 hours old and tests with midges should be started with second or third instar larvae. The results should be the 48-hour EC50 based on percentage of organisms killed or immobilized. If such an EC50 is not available for a test, the 48-hour LC50 should be used in place of the desired 48-hour EC50. An EC50 or LC50 of longer than 48 hours can be used as long as the animals were not fed and the control animals were acceptable at the end of the test.

2. The results of a test with embryos and larvae of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones should be the 96-hour EC50 based on percentage of organisms with incompletely developed shells plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from the test, the lowest of the following should be used in place of the desired 96-hour EC50: 48- to 96-hour EC50s based on percentage of organisms with incompletely developed shells plus percentage of organisms killed, 48- to 96-hour EC50s based upon percentage of organisms with incompletely developed shells, and 48- to 96-hour LC50s.

3. The result of tests with all other aquatic animal species and older life stages of barnacles, bivalve molluscs (clams, mussels, oysters and scallops), sea urchins, lobsters, crabs, shrimp and abalones should be the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized plus percentage of organisms killed. If such an EC50 is not available from a test, of the values that are available from a test the lower of the following should be used in place of the desired 96-hour EC50: the 96-hour EC50 based on percentage of organisms exhibiting loss of equilibrium plus percentage of organisms immobilized and the 96-hour LC50.

4. Tests whose results take into account the number of young produced, such as most tests with protozoans, are not considered acute tests, even if the duration was 96 hours or less.

5. If the tests were conducted properly, acute values reported as "greater than" values and those which are above the solubility of the test material should be used, because rejection of such acute values would bias the Final Acute Value by eliminating acute values for resistant species.

F. If the acute toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section V of this appendix.

G. The agreement of the data within and between species must be considered. Acute values that appear to be questionable in comparison with other acute and chronic data for the same species and for other species in the same genus must not be used. For example, if the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is probably appropriate.

H. If the available data indicate that one or more life stages are at least a factor of two or more resistant than one or more other life stages of the same species, the data for the more resistant life stages must not be used in the calculation of the Species Mean Acute Value because a species cannot be considered protected from acute toxicity if all of the life stages are not protected.

I. For each species for which at least one acute value is available, the Species Mean Acute Value (SMAV) should be calculated as the geometric mean of the results of all flow-through tests in which the concentrations of test material were measured. For a species for which no such result is available, the SMAV shall be calculated as the geometric of all available acute values, i.e., results of flow-through tests in which the concentrations were not measured and results of static and renewal tests based on initial concentrations (nominal concentrations are acceptable for most test materials if measured concentrations are not available) of test material.

Note 1: Data reported by original investigators must not be rounded off. Results of all intermediate calculations must be rounded off to no fewer than four significant digits.

Note 2: The geometric mean of N numbers is the Nth root of the product of the N numbers. Alternatively, the geometric mean can be calculated by adding the logarithms of the N numbers, dividing the sum by N, and taking the antilog of the quotient. The geometric mean of two numbers is the square root of the product of the two numbers, and the geometric mean of one number is that number. Either natural (base e) or common (base 10) logarithms can be used to calculate geometric means as long as they are used consistently within each set of data, i.e., the antilog used must match the logarithms used.

Note 3: Geometric means, rather than arithmetic means are used here because the distributions of sensitivities of individual organisms in toxicity tests on most materials and the distributions of sensitivities of species within a genus are more likely to be lognormal than normal. Similarly, geometric means are used for acute-chronic ratios because quotients are likely to be closer to lognormal than normal distributions. In addition, division of the geometric mean of a set of numerators by the geometric mean of the set of denominators will result in the geometric mean of the set of corresponding quotients.

J. For each genus for which one or more SMAVs are available, the Genus Mean Acute Value (GMAV) shall be calculated as the geometric mean of the SMAVs available for the genus.

K. Order the GMAVs from high to low.

L. Assign ranks, R, to the GMAVs from "1" for the lowest to "N" for the highest. If two or more GMAVs are identical, assign them successive ranks.

M. Calculate the cumulative probability, P, for each GMAV as R/(N+1).

N. Select the four GMAVs which have cumulative probabilities closest to 0.05 (if there are less than 59 GMAVs, these will always be the four lowest GMAVs).

O. Using the selected GMAVs, and Ps, calculate.

$$S^2 = \frac{\sum\left((\ln \text{GMAV})^2\right) - \frac{\left(\sum(\ln \text{GMAV})\right)^2}{4}}{\sum(P) - \frac{\left(\sum\left(\sqrt{P}\right)\right)^2}{4}}$$

$$L = \frac{\sum(\ln \text{GMAV}) - S\left(\sum\left(\sqrt{P}\right)\right)}{4}$$

$$A = S\left(\sqrt{0.05}\right) + L$$

$$FAV = e^A$$

Note: Natural logarithms (logarithms to base e, denoted as ln) are used herein merely because they are easier to use on some hand calculators and computers than common (base 10) logarithms. Consistent use of either will produce the same result.

P. If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured is lower than the calculated Final Acute Value (FAV), then that geometric mean must be used as the FAV instead of the calculated FAV.

Q. See section VI of this appendix.

V. Final Acute Equation

A. When enough data are available to show that acute toxicity to two or more species is similarly related to a water quality characteristic, the relationship shall be taken into account as described in sections V.B through G of this appendix or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

B. For each species for which comparable acute toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the acute toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as pH, temperature, or salinity, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section.

C. Decide whether the data for each species is useful, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be useful if it is consistent with other information and if the two points cover a broad enough range of the water quality characteristic. In addition, acute values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus shall not be used. For example, if after adjustment for the water quality characteristic, the acute values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is probably appropriate. If useful slopes are not available for at least one fish and one invertebrate or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between acute toxicity and the water quality characteristic, return to section IV.G of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

D. Individually for each species calculate the geometric mean of the available acute values and then divide each of the acute values for a species by the mean for the species. This normalizes the acute values so that the geometric mean of the normalized values for each species individually and for any combination of species is 1.0.

E. Similarly normalize the values of the water quality characteristic for each species individually.

F. Individually for each species perform a least squares regression of the normalized acute values of the water quality characteristic. The resulting slopes and 95 percent confidence limits will be identical to those obtained in section B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

G. Treat all of the normalized data as if they were all for the same species and perform a least squares regression of all of the normalized acute values on the corresponding normalized values of the water quality characteristic to obtain the pooled acute slope, V, and its 95 percent confidence limits. If all of the normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

H. For each species calculate the geometric mean, W, of the acute toxicity values and the geometric mean, X, of the values of the water quality characteristic. (These were calculated in sections D and E of this appendix.)

I. For each species, calculate the logarithm, Y, of the Species Mean Acute Value (SMAV) at a selected value, Z, of the water quality characteristic using the equation:

$$Y = \ln W - V(\ln X - \ln Z)$$

J. For each species calculate the SMAV at X using the equation:

$$SMAV = e^{Y}$$

Note: Alternatively, the SMAVs at Z can be obtained by skipping step H above, using the equations in steps I and J to adjust each acute value individually to Z, and then calculating the geometric mean of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted acute values for each species.

K. Obtain the Final Acute Value at Z by using the procedure described in sections IV.J through O of this appendix.

L. If for a commercially of recreationally important species of the Great Lakes System the geometric mean of the acute values at Z from flow through tests in which the concentrations of the test material were measured is lower than the Final Acute Value at Z, then the geometric mean must be used as the Final Acute Value instead of the Final Acute Value.

M. The Final Acute Equation is written as:

$$\text{Final Acute Value} = e^{(V[\ln(\text{water quality characteristic})]+A-V[\ln Z])}$$

where:

V=pooled acute slope, and A=ln(Final Acute Value at Z).

Because V, A, and Z are known, the Final Acute Value can be calculated for any selected value of the water quality characteristic.

VI. Final Chronic Value

A. Depending on the data that are available concerning chronic toxicity to aquatic animals, the Final Chronic Value might be calculated in the same manner as the Final Acute Value or by dividing the Final Acute Value by the Final Acute-Chronic Ratio. In some cases, it may not be possible to calculate a Final Chronic Value for Tier I.

Note: As the name implies, the acute-chronic ratio (ACR) is a way of relating acute and chronic toxicities. The acute-chronic ratio is basically the inverse of the application factor, but this new name is better because it is more descriptive and should help prevent confusion between "application factors" and "safety factors." Acute-chronic ratios and application factors are ways of relating the acute and chronic toxicities of a material to aquatic organisms. Safety factors are used to provide an extra margin of safety beyond the known or estimated sensitivities of aquatic organisms. Another advantage of the acute-chronic ratio is that it will usually be greater than one; this should avoid the confusion as to whether a large application factor is one that is close to unity or one that has a denominator that is much greater than the numerator.

B. Chronic values shall be based on results of flow-through (except renewal is acceptable for daphnids) chronic tests in which the concentration of test material in the test solutions were properly measured at appropriate times during the test.

C. Results of chronic tests in which survival, growth, or reproduction in the control treatment was unacceptably low shall not be used. The limits of acceptability will depend on the species.

D. Results of chronic tests conducted in unusual dilution water, e.g., dilution water in which total organic carbon or particulate matter exceeded five mg/L, shall not be used, unless a relationship is developed between chronic toxicity and organic carbon or particulate matter, or unless data show that organic carbon, particulate matter, etc., do not affect toxicity.

E. Chronic values must be based on endpoints and lengths of exposure appropriate to the species. Therefore, only results of the following kinds of chronic toxicity tests shall be used:

1. Life-cycle toxicity tests consisting of exposures of each of two or more groups of individuals of a species to a different concentration of the test material throughout a life cycle. To ensure that all life stages and life processes are exposed, tests with fish should begin with embryos or newly hatched young less than 48 hours old, continue through maturation and reproduction, and should end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Tests with daphnids should begin with young less than 24 hours old and last for not less than 21 days, and for Ceriodaphnia not less than seven days. Tests with mysids should begin with young less than 24 hours old and continue until seven days past the median time of first brood release in the controls. For fish, data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability. For daphnids, data should be obtained and analyzed on survival and young per female. For mysids, data should be obtained and analyzed on survival, growth, and young per female.

2. Partial life-cycle toxicity tests consist of exposures of each of two more groups of individuals of a species of fish to a different concentration of the test material through most portions of a life cycle. Partial life-cycle tests are allowed with fish species that require more than a year to reach sexual maturity, so that all major life stages can be exposed to the test material in less than 15 months. Exposure to the test material should begin with immature juveniles at least two months prior to active gonad development, continue through maturation and reproduction, and end not less than 24 days (90 days for salmonids) after the hatching of the next generation. Data should be obtained and analyzed on survival and growth of adults and young, maturation of males and females, eggs spawned per female, embryo viability (salmonids only), and hatchability.

3. Early life-stage toxicity tests consisting of 28- to 32-day (60 days post hatch for salmonids) exposures of the early life stages of a species of fish from shortly after fertilization through embryonic, larval, and early juvenile development. Data should be obtained and analyzed on survival and growth.

Note: Results of an early life-stage test are used as predictions of results of life-cycle and partial life-cycle tests with the same species. Therefore, when results of a life-cycle or partial life-cycle test are available, results of an early life-stage test with the same species should not be used. Also, results of early life-stage tests in which the incidence of mortalities or abnormalities increased substantially near the end of the test shall not be used because the results of such tests are possibly not good predictions of comparable life-cycle or partial life-cycle tests.

F. A chronic value may be obtained by calculating the geometric mean of the lower and upper chronic limits from a chronic test or by analyzing chronic data using regression analysis.

1. A lower chronic limit is the highest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on any of the specified biological measurements; and

c. Below which no tested concentration caused an unacceptable effect.

2. An upper chronic limit is the lowest tested concentration:

a. In an acceptable chronic test;

b. Which did not cause an unacceptable amount of adverse effect on one or more of the specified biological measurements; and

c. Above which all tested concentrations also caused such an effect.

Note: Because various authors have used a variety of terms and definitions to interpret and report results of chronic tests, reported results should be reviewed carefully. The amount of effect that is considered unacceptable is often based on a statistical hypothesis test, but might also be defined in terms of a specified percent reduction from the controls. A small percent reduction (e.g., three percent) might be considered acceptable even if it is statistically significantly different from the control, whereas a large percent reduction (e.g., 30 percent) might be considered unacceptable even if it is not statistically significant.

G. If the chronic toxicity of the material to aquatic animals has been shown to be related to a water quality characteristic such as hardness or particulate matter for freshwater animals, refer to section VII of this appendix.

H. If chronic values are available for species in eight families as described in section III.B.1 of this appendix, a Species Mean Chronic Value (SMCV) shall be calculated for each species for which at least one chronic value is available by calculating the geometric mean of all chronic values available for the species, and appropriate Genus Mean Chronic Values shall also be

calculated. The Final Chronic Value shall be obtained using the procedure described in sections IV.J through O of this appendix. See section VI.M of this appendix.

I. For each chronic value for which at least one corresponding appropriate acute value is available, calculate an acute-chronic ratio, using for the numerator the geometric mean of the results of all acceptable flow-through (except static is acceptable for daphnids and midges) acute tests in the same dilution water in which the concentrations are measured. For fish, the acute test(s) should be conducted with juveniles. The acute test(s) should be part of the same study as the chronic test. If acute tests are not conducted as part of the same study, acute tests conducted in the same laboratory and dilution water, but in a different study, may be used. If no such acute tests are available, results of acute tests conducted in the same dilution water in a different laboratory may be used. If no such acute tests are available, an acute-chronic ratio shall not be calculated.

J. For each species, calculate the Species Mean Acute-Chronic Ratio as the geometric mean of all acute-chronic ratios available for that species. Preference should be given to freshwater (versus saltwater) species acute-chronic ratios when calculating a Final Acute-Chronic Ratio. If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.

K. For some materials, the acute-chronic ratio seems to be the same for all species, but for other materials the ratio seems to increase or decrease as the Species Mean Acute Value (SMAV) increases. Thus the Final Acute-Chronic Ratio can be obtained in four ways, depending on the data available:

1. If the species mean acute-chronic ratio seems to increase or decrease as the SMAVs increase, the Final Acute-Chronic Ratio shall be calculated as the geometric mean of the acute-chronic ratios for species whose SMAVs are close to the Final Acute Value.

2. If no major trend is apparent and the acute-chronic ratios for all species are within a factor of ten, the Final Acute-Chronic Ratio shall be calculated as the geometric mean of all of the Species Mean Acute-Chronic Ratios for both freshwater and saltwater species.

3. For acute tests conducted on metals and possibly other substances with embryos and larvae of barnacles, bivalve molluscs, sea urchins, lobsters, crabs, shrimp, and abalones (see section IV.E.2 of this appendix), it is probably appropriate to assume that the acute to chronic ratio is two. Chronic tests are very difficult to conduct with most such species, but it is likely that the sensitivities of embryos and larvae would determine the results of life cycle tests. Thus, if the lowest available SMAVs are determined with embryos and larvae of such species, the Final Chronic Value is equal to the Criterion Maximum Concentration (see section VI of this appendix).

4. If the most appropriate species mean acute-chronic ratios are less than 2.0, and especially if they are less than 1.0, acclimation has probably occurred during the chronic test. In this situation, because continuous exposure and acclimation cannot be assured to provide adequate protection in field situations, the Final Acute-Chronic Ratio should be assumed to be two, so that the Final Chronic Value is equal to the Criterion Maximum Concentration. (See section X.B of this appendix)

If the available species mean acute-chronic ratios do not fit one of these cases, a Final Acute-Chronic Ratio probably cannot be obtained and a Final Chronic Value probably cannot be calculated for Tier I.

Preference shall be given to freshwater (versus saltwater) species acute-chronic ratios when calculating Final Acute-Chronic Ratio. If the minimum acute-chronic ratio data requirements (as described in section III.B.2 of this appendix) are not met with freshwater data alone, saltwater data may be used.

L. Calculate the Final Chronic Value by dividing the Final Acute Value by the Final Acute-Chronic Ratio. If there is a Final Acute Equation rather than a Final Acute Value, see also section V of this appendix.

M. If the Species Mean Chronic Value of a commercially or recreationally important species of the Great Lakes System is lower than the calculated Final Chronic Value, then that Species Mean Chronic Value must be used as the Final Chronic Value instead of the calculated Final Chronic Value.

N. See section VIII of this appendix.

VII. Final Chronic Equation

A. A Final Chronic Equation can be derived in two ways. The procedure described here in section VII.A of this appendix will result in the chronic slope being the same as the acute slope. The procedure described in sections VII.B through N of this appendix will usually result in the chronic slope being different from the acute slope.

1. If acute-chronic ratios are available for enough species at enough values of the water quality characteristic to indicate that the acute-chronic ratio is probably the same for all species and is probably independent of the water quality characteristic, calculate the Final Acute-Chronic Ratio as the geometric mean of the available Species Mean Acute-Chronic Ratios.

2. Calculate the Final Chronic Value at the selected value Z of the water quality characteristic by dividing the Final Acute Value at Z. (see section V.M of this appendix) by the Final Acute-Chronic Ratio.

3. Use V=pooled acute slope (see section V.M of this appendix)

as

L=pooled chronic slope.

4. See section VII.M of this appendix.

B. When enough data are available to show that chronic toxicity to at least one species is related to a water quality characteristic, the relationship should be taken into account as described in sections B through G below or using analysis of covariance. The two methods are equivalent and produce identical results. The manual method described below provides an understanding of this application of covariance analysis, but computerized versions of covariance analysis are much more convenient for analyzing large data sets. If two or more factors affect toxicity, multiple regression analysis shall be used.

C. For each species for which comparable chronic toxicity values are available at two or more different values of the water quality characteristic, perform a least squares regression of the chronic toxicity values on the corresponding values of the water quality characteristic to obtain the slope and its 95 percent confidence limits for each species.

Note: Because the best documented relationship is that between hardness and acute toxicity of metals in fresh water and a log-log relationship fits these data, geometric means and natural logarithms of both toxicity and water quality are used in the rest of this section. For relationships based on other water quality characteristics, such as pH, temperature, or salinity, no transformation or a different transformation might fit the data better, and appropriate changes will be necessary throughout this section. It is probably preferable, but not necessary, to use the same transformation that was used with the acute values in section V of this appendix.

D. Decide whether the data for each species is useful, taking into account the range and number of the tested values of the water quality characteristic and the degree of agreement within and between species. For example, a slope based on six data points might be of limited value if it is based only on data for a very narrow range of values of the water quality characteristic. A slope based on only two data points, however, might be more useful if it is consistent with other information and if the two points cover a broad range of the water quality characteristic. In addition, chronic values that appear to be questionable in comparison with other acute and chronic data available for the same species and for other species in the same genus probably should not be used. For example, if after adjustment for the water quality characteristic, the chronic values available for a species or genus differ by more than a factor of 10, rejection of some or all of the values is probably appropriate. If a useful chronic slope is not available for at least one species or if the available slopes are too dissimilar or if too few data are available to adequately define the relationship between chronic toxicity and the water quality characteristic, it might be appropriate to assume that the chronic slope is the same as the acute slope, which is equivalent to assuming that the acute-chronic ratio is independent of the water quality characteristic. Alternatively, return to section VI.H of this appendix, using the results of tests conducted under conditions and in waters similar to those commonly used for toxicity tests with the species.

E. Individually for each species calculate the geometric mean of the available chronic values and then divide each chronic value for a species by the mean for the species. This normalizes the chronic values so that the geometric mean of the normalized values for each species individually, and for any combination of species, is 1.0.

F. Similarly, normalize the values of the water quality characteristic for each species individually.

G. Individually for each species perform a least squares regression of the normalized

chronic toxicity values on the corresponding normalized values of the water quality characteristic. The resulting slopes and the 95 percent confidence limits will be identical to those obtained in section VII.B of this appendix. Now, however, if the data are actually plotted, the line of best fit for each individual species will go through the point 1,1 in the center of the graph.

H. Treat all of the normalized data as if they were all the same species and perform a least squares regression of all of the normalized chronic values on the corresponding normalized values of the water quality characteristic to obtain the pooled chronic slope, L, and its 95 percent confidence limits.

If all normalized data are actually plotted, the line of best fit will go through the point 1,1 in the center of the graph.

I. For each species, calculate the geometric mean, M, of the toxicity values and the geometric mean, P, of the values of the water quality characteristic. (These are calculated in sections VII.E and F of this appendix.)

J. For each species, calculate the logarithm, Q, of the Species Mean Chronic Value at a selected value, Z, of the water quality characteristic using the equation:

$$Q = \ln M - L(\ln P - \ln Z)$$

Note: Although it is not necessary, it is recommended that the same value of the water quality characteristic be used here as was used in section VI of this appendix.

K. For each species, calculate a Species Mean Chronic Value at Z using the equation:

$$SMCV = e^{Q}$$

Note: Alternatively, the Species Mean Chronic Value at Z can be obtained by skipping section VII.J of this appendix, using the equations in sections VII.J and K of this appendix to adjust each chronic value individually to Z and then calculating the geometric means of the adjusted values for each species individually. This alternative procedure allows an examination of the range of the adjusted chronic values for each species.

L. Obtain the Final Chronic Value at Z by using the procedure described in sections IV.J through O of this appendix.

M. If the Species Mean Chronic Value at Z of a commercially or recreationally important species of the Great Lakes System is lower than the calculated Final Chronic Value at Z, then that Species Mean Chronic Value shall be used as the Final Chronic Value at Z instead of the calculated Final Chronic Value.

N. The Final Chronic Equation is written as:

$$\text{Final Chronic Value} = e^{(L[\ln(\text{water quality characteristic})]+\ln S-L[\ln Z])}$$

where:

L=pooled chronic slope and S=Final Chronic Value at Z.

Because L, S, and Z are known, the Final Chronic Value can be calculated for any selected value of the water quality characteristic.

VIII. Final Plant Value

A. Appropriate measures of the toxicity of the material to aquatic plants are used to compare the relative sensitivities of aquatic plants and animals. Although procedures for conducting and interpreting the results of toxicity tests with plants are not well-developed, results of tests with plants usually indicate that criteria which adequately protect aquatic animals and their uses will probably also protect aquatic plants and their uses.

B. A plant value is the result of a 96-hour test conducted with an alga or a chronic test conducted with an aquatic vascular plant.

Note: A test of the toxicity of a metal to a plant shall not be used if the medium contained an excessive amount of a complexing agent, such as EDTA, that might affect the toxicity of the metal. Concentrations of EDTA above 200 ug/L should probably be considered excessive.

C. The Final Plant Value shall be obtained by selecting the lowest result from a test with an important aquatic plant species in which the concentrations of test material are measured and the endpoint is biologically important.

IX. Other Data

Pertinent information that could not be used in earlier sections might be available concerning adverse effects on aquatic organisms and their uses. The most important of these are data on cumulative and delayed toxicity, reduction in survival, growth, or reproduction, or any other adverse effect that has been shown to be biologically important. Especially important are data for species for which no other data are available. Data from behavioral, biochemical, physiological, microcosm, and field studies might also be available. Data might be available from tests conducted in unusual dilution water (see sections IV.D and VI.D of this appendix), from chronic tests in which the concentrations were not measured (see section VI.B of this appendix), from tests with previously exposed organisms (see section II.F of this appendix), and from tests on formulated mixtures or emulsifiable concentrates (see section II.D of this appendix). Such data might affect a criterion if the data were obtained with an important species, the test concentrations were measured, and the endpoint was biologically important.

X. Criterion

A. A criterion consists of two concentrations: the Criterion Maximum Concentration and the Criterion Continuous Concentration.

B. The Criterion Maximum Concentration (CMC) is equal to one-half the Final Acute Value.

C. The Criterion Continuous Concentration (CCC) is equal to the lowest of the Final Chronic Value or the Final Plant Value (if available) unless other data (see section IX of this appendix) show that a lower value should be used. If toxicity is related to a water quality characteristic, the CCC is obtained from the Final Chronic Equation or Final Plant Value (if available) that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (see section IX) show that a lower value should be used.

D. Round both the CMC and the CCC to two significant digits.

E. The criterion is stated as:

The procedures described in the Tier I methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms and their uses should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) µg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) µg/L more than once every three years on the average.

where:

(1) = insert name of material
(2) = insert the Criterion Continuous Concentration
(3) = insert the Criterion Maximum Concentration

XI. Final Review

A. The derivation of the criterion should be carefully reviewed by rechecking each step of the Guidance. Items that should be especially checked are:

1. If unpublished data are used, are they well documented?
2. Are all required data available?
3. Is the range of acute values for any species greater than a factor of 10?
4. Is the range of Species Mean Acute Values for any genus greater than a factor of 10?
5. Is there more than a factor of 10 difference between the four lowest Genus Mean Acute Values?
6. Are any of the lowest Genus Mean Acute Values questionable?
7. Is the Final Acute Value reasonable in comparison with the Species Mean Acute Values and Genus Mean Acute Values?
8. For any commercially or recreationally important species of the Great Lakes System, is the geometric mean of the acute values from flow-through tests in which the concentrations of test material were measured lower than the Final Acute Value?
9. Are any of the chronic values questionable?
10. Are any chronic values available for acutely sensitive species?
11. Is the range of acute-chronic ratios greater than a factor of 10?
12. Is the Final Chronic Value reasonable in comparison with the available acute and chronic data?
13. Is the measured or predicted chronic value for any commercially or recreationally

important species of the Great Lakes System below the Final Chronic Value?

14. Are any of the other data important?

15. Do any data look like they might be outliers?

16. Are there any deviations from the Guidance? Are they acceptable?

B. On the basis of all available pertinent laboratory and field information, determine if the criterion is consistent with sound scientific evidence. If it is not, another criterion, either higher or lower, shall be derived using appropriate modifications of this Guidance.

Methodology for Deriving Aquatic Life Values: Tier II

XII. Secondary Acute Value

If all eight minimum data requirements for calculating an FAV using Tier I are not met, a Secondary Acute Value (SAV) for the waters of the Great Lakes basin shall be calculated for a chemical as follows:

To calculate a SAV, the lowest GMAV in the database is divided by the Secondary Acute Factor (SAF) (Table A–1 of this appendix) corresponding to the number of satisfied minimum data requirements listed in the Tier I methodology (section III.B.1 of this appendix). If all eight minimum data requirements are satisfied, a Tier I criterion calculation may be possible. In order to calculate a SAV, the database must contain, at a minimum, a genus mean acute value (GMAV) for one of the following three genera in the family Daphnidae—*Ceriodaphnia sp., Daphnia sp.*, or *Simocephalus sp.*

If appropriate, the SAV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XIII. Secondary Acute-Chronic Ratio

If three or more experimentally determined acute-chronic ratios (ACRs), which are acceptable based on Tier I, are available for the chemical, determine the Final Acute-Chronic Ratio (FACR) using the procedure described in Tier I. If fewer than three acceptable experimentally determined ACRs are available, use enough assumed ACRs of 18 so that the total number of ACRs equals three. Calculate the Secondary Acute-Chronic Ratio (SACR) as the geometric mean of the three ACRs. Thus, if no experimentally determined acute-chronic ratios are available, the SACR is 18.

XIV. Secondary Chronic Value

Calculate the Secondary Chronic Value (SCV) using one of the following:

A. $$SCV = \frac{FAV}{SACR}$$ (use FAV from Tier I)

B. $$SCV = \frac{SAV}{FACR}$$

C. $$SCV = \frac{SAV}{SACR}$$

If appropriate, the SCV will be made a function of a water quality characteristic in a manner similar to that described in Tier I.

XV. Commercially or Recreationally Important Species

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the acute values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SAV, then that geometric mean must be used as the SAV instead of the calculated SAV.

If for a commercially or recreationally important species of the Great Lakes System the geometric mean of the chronic values from flow-through tests in which the concentrations of the test materials were measured is lower than the calculated SCV, then that geometric mean must be used as the SCV instead of the calculated SCV.

XVI. Tier II Value

A. Secondary Value shall consist of two concentrations: the Secondary Maximum Concentration (SMC) and the Secondary Continuous Concentration (SCC).

B. The SMC is equal to one-half of the SAV.

C. The SCC is equal to the lowest of the SCV or the Final Plant Value, if available, unless other data (See section IX of this appendix) show that a lower value should be used.

If toxicity is related to a water quality characteristic, the SCC is obtained from the Secondary Chronic Equation or Final Plant Value, if available, that results in the lowest concentrations in the usual range of the water quality characteristic, unless other data (See section IX of this appendix) show that a lower value should be used.

D. Round both the SMC and the SCC to two significant digits.

E. The value is stated as:

The procedures described in the Tier II methodology indicate that, except possibly where a locally important species is very sensitive, aquatic organisms should not be affected unacceptably if the four-day average concentration of (1) does not exceed (2) µg/L more than once every three years on the average and if the one-hour average concentration does not exceed (3) µg/L more than once every three years on the average.

Where:

(1)=insert name of material
(2)=insert the Secondary Continuous Concentration
(3)=insert the Secondary Maximum Concentration

XVII. Appropriate Modifications

On the basis of all available pertinent laboratory and field information, determine if the value is consistent with sound scientific evidence. If it is not, another value, either higher or lower, must be derived using appropriate modifications of these procedures.

XVIII. Availablity of Information

The most recent secondary values shall be compiled on an annual basis by EPA Region V Water Division and be available for distribution to the public.

Tables to Appendix A to Part 132

TABLE A–1.—SECONDARY ACUTE FACTORS

Number of satisfied minimum data requirements	AF
1	20
2	13
3	9.8
4	6.5
5	5.0
6	4.0
7	3.6

Appendix B to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Bioaccumulation Factors

I. Introduction

The purpose of this methodology is to determine bioaccumulation factors to be used in the calculation of Great Lakes Water Quality Guidance (GLWQG) human health and wildlife Tier I criteria and Tier II values. The BAFs for human health criteria and values will also be used to identify the Bioaccumulative Chemicals of Concern (BCCs) to be considered under the Great Lakes Initiative (GLI) programs.

Bioaccumulation reflects uptake of a substance by aquatic organisms exposed to the substance through all routes, as would occur in nature. Bioconcentration reflects uptake of a substance by aquatic organisms exposed to the substance only from the surrounding water medium. Both bioaccumulation factors (BAFs) and bioconcentration factors (BCFs) are

proportionality constants, relating the concentration of a substance in aquatic organisms to its concentration in the surrounding water. BAFs, rather than BCFs, will be used to calculate Tier I criteria and Tier II values because BAFs represent the bioaccumulation that occurs in natural aquatic systems. Measured BAFs will be used when possible; otherwise, predicted BAFs will be calculated by multiplying a measured or predicted BCF by a food chain multiplier (FCM).

II. Definitions

Bioaccumulation. The uptake and retention of a substance by an aquatic organism from its surrounding medium and food.

Bioaccumulation factor (BAF). The ratio (in L/kg) of a substance's concentration in tissue to its concentration in the surrounding water in situations where both the organism and its food are exposed and the ratio does not change substantially over time.

Bioconcentration. The uptake and retention of a substance by an aquatic organism from the surrounding water only, through gill membranes or other external body surfaces.

Depuration. The loss of a substance from an aquatic organism.

Food Chain Multiplier (FCM). A factor by which a BCF is multiplied to obtain a BAF; or, the ratio of the BAF to the BCF.

Octanol-water partition coefficient (K_{ow}). The ratio of the concentration of a substance in the octanol phase to its concentration in the aqueous phase in an equilibrated two-phase octanol-water system.

Steady-State Bioconcentration Factor (BCF). The ratio (L/kg) of a substance's concentration in tissue to its concentration in the surrounding water, in situations where the organism is exposed through the water only, and the ratio does not change substantially over time; that is, a steady-state BCF exists when uptake and depuration are equal. In this methodology whenever the term BCF is used, steady state is implied.

Uptake. The sorption of a substance into or onto an aquatic organism.

III. Overview of Procedure

Bioaccumulation factors are derived in the three ways listed below from most preferred to least preferred:

A. A measured BAF based on a field study, especially if the field study was conducted on the Great Lakes with fish at or near the top of the aquatic food chain.

B. A predicted BAF that is the product of a measured BCF from a laboratory study and a food chain multiplier (FCM).

C. A predicted BAF for organic chemicals which is the product of a BCF estimated from a log K_{ow} and a FCM, where log means logarithm to the base 10.

BAFs for a chemical should be calculated by as many of the three methods as available data allow for comparative purposes. The BAF selected is based on the stated preferences unless there is a valid reason for selecting an alternative BAF. For most inorganic chemicals, and many organic chemicals, the FCM will be 1.0; that is, bioaccumulation and bioconcentration are equal. The lipid content of the test fish will be used to normalize BAFs and BCFs for organic chemicals so that data from different tissues and fish species can be integrated.

Fish are the dominant aquatic species consumed by humans in the Great Lakes basin. Thus, BAFs for human health Tier I criteria and Tier II values will be based on fish. Because Great Lakes basin wildlife include many piscivorous species, BAFs for wildlife criteria and values will generally be based on fish data as well. On a case-specific basis, wildlife BAFs may be weighted to reflect the proportion of plants, invertebrates, and fish in the diet of the species to be protected.

IV. Review and Selection of Data

A. *Data Sources.* Measured BAFs and BCFs are assembled from available sources including the following:

1. EPA Ambient Water Quality Criteria documents issued after January 1, 1980.
2. AQUIRE data base.
3. Published scientific literature.
4. Reports issued by EPA or other reliable sources.
5. Unpublished data.

B. *Data Review and Selection.* Measured BCFs and, if applicable, measured BAFs should meet the procedural and quality assurance requirements specified in the ASTM (1990) "Standard Practice for Conducting Bioconcentration Tests with Fishes and Saltwater Bivalve Molluscs", and in the U.S. EPA guidance contained in Stephan et al. (1985) "Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and Their Uses". In particular. the following should be met:

1. The bioconcentration factor is steady-state, or steady-state BCF can be estimated.
2. The concentration of the substance did not have an adverse effect on the test organisms.
3. The concentration of the substance in the water was measured and was relatively constant during the steady-state time period. The concentration should be averaged over the period during which steady-state conditions were achieved. All average (mean) values are geometric means unless specified otherwise.
4. For measured BCFs, the organisms were exposed to the substance using a flow-through or renewal procedure.
5. For organic chemicals, the percent lipid was measured in, or can be reliably determined for, the test organisms.

This methodology provides overall guidance for the derivation of BAFs, but it cannot cover all the decisions that must be made in the review and selection of acceptable data. Professional judgment is required throughout the process. A degree of uncertainty is associated with the determination of any BAF or BCF. The amount of uncertainty involved in deriving a BAF depends on both the quality of data available and the method used to derive the BAF.

Field-measured BAFs should be based on fish species, preferably living in the Great Lakes at or near the top of the aquatic food chain (trophic level 3 or 4). This is particularly true for organic chemicals with log K_{ow} values greater than four. The conditions of the field study should not be so unique that the BAF is not applicable to other locations where the criteria and values will apply.

Laboratory-measured BCFs also should be based on fish species, but BCFs for molluscs and other invertebrates may be used with caution. For example, because invertebrates metabolize some chemicals less efficiently than vertebrates, the BCF obtained with invertebrates for such chemicals will be higher than the BCF obtained with fish on a lipid basis.

The percent lipid content of the test organisms and the analytical method used to measure lipids should be reported as part of a BAF or BCF study on organic chemicals. An average lipid value representative of tissue in the test organisms should be used. If percent lipid is not reported for the test organisms in the original study, it may be obtained from the author; or, in the case of a laboratory study, lipid data for the same laboratory population of test organisms that were used in the original study may be used.

If measured BCFs for a substance vary with the test concentration of the substance in a laboratory test, the BCF measured at the lowest test concentration that is above concentrations that exist in the control water should be used; i.e., do not use the BCF from a control treatment.

BAFs and BCFs should be used only if they are expressed on a wet weight basis. BAFs and BCFs reported on a dry weight basis should be converted to wet weight only if a conversion factor was determined for the test organisms or comparable organisms from the same study.

Hereinafter in this methodology, the terms BAF and BCF refer to those BAFs and BCFs that are consistent with the above provisions for data review and selection.

V. Determination of BAFs for Inorganic Chemicals

BAFs are assumed to be equal to BCFs for most inorganic substances. However, a food chain multiplier may be applicable to some metals, for example, if an organometallic form of the metal biomagnifies.

Concentrations of an inorganic substance in a BAF or BCF study should be greater than normal background levels and greater than levels required for normal nutrition of the test species if the substance is a micronutrient, while still below levels which adversely affect the species. Bioaccumulation of inorganic substances may be inappropriately overestimated if concentrations are at or below normal background levels due to, for example, nutritional requirements of the test organisms.

A. BAF for Human Health Criteria and Values

1. BAFs and BCFs used to determine human health BAFs should be based on edible tissue (e.g., muscle) of freshwater fish unless it can be demonstrated that whole body BAFs or BCFs are similar to edible tissue BAFs or BCFs. BCFs for non-fish species and non-edible tissues of fish are generally higher than for muscle of fish.

These other BCFs and BAFs should only be used to set upper limits on the BCF or BAF for edible tissues. Plant BCFs and BAFs should not be used for human health criteria and values.

2. If one or more measured BAFs are available for an inorganic chemical, the geometric mean of those BAFs will be used.

3. A predicted BAF used to derive human health criteria and values equals an edible-portion BCF times a food chain multiplier. If more than one edible-portion BCF is available, the geometric mean of those values will be used. The food chain multiplier will be 1.0 unless chemical specific biomagnification data support using a multiplier other than 1.0.

B. BAF for Wildlife Criteria and Values

1. BAFs and BCFs used to determine wildlife criteria and values should be based on whole-body fish data unless it can be demonstrated that, BAFs or BCFs for edible tissue, are similar to whole body BAFs or BCFs. BCFs and BAFs for non-fish species and non-edible tissues of fish are generally higher than for muscle of fish. The BCFs and BAFs for non-fish species and non-edible tissues of fish should only be used to set lower limits on the desired BCF or BAF for whole body.

2. If one or more measured BAFs are available, the geometric mean of those BAFs will be used.

3. A predicted BAF used to derive wildlife criteria and values equals a whole-body BCF times a food chain multiplier. If more than one whole-body BCF is available, the geometric mean will be used. The food chain multiplier will be 1.0 unless chemical specific biomagnification data support using a multiplier other than 1.0.

4. BAFs or BCFs, used to determine wildlife criteria and values, for whole-body fish, invertebrates and aquatic plants may be considered on a case-by-case basis. If used, they should be used in proportion to the percent-by-weight of invertebrate or plant material consumed by the wildlife species to be protected.

VI. Determination of BAFs for Organic Chemicals

A. Lipid Normalization

For lipophilic organic chemicals, BAFs and BCFs are assumed to be directly proportional to the percent lipid from one tissue to another and from one aquatic species to another. Percent lipid data are used to convert reported BAFs and BCFs to BAFs and BCFs appropriate for the fisheries of the Great Lakes basin. Percent lipid data are also used to determine human health and wildlife BAFs from the same data.

The percent lipid of the test organism (whole body or edible tissue) should be obtained from the BAF or BCF study. BAFs and BCFs are normalized to one percent lipid by dividing the BAFs or BCFs by the mean percent lipid. Both whole body and edible tissue BAFs and BCFs are normalized using the respective whole body and edible tissue percent lipid values. Unless comparability can be determined, the percent lipid should be determined on the test organisms.

B. Food Chain Multiplier

In the absence of measured BAFs for organic chemicals, a food chain multiplier (FCM) is used to predict the BAF. The appropriate FCM is selected from Table 1 based on the chemical's log K_{ow}. A FCM greater than 1.0 is applicable to most lipophilic organic chemicals with log K_{ow} values of four or more. For human health BAFs, a FCM from Table 1 for trophic level 4 (top predator fish) is used. For wildlife BAFs, FCMs for trophic levels 3 (small fish) and 4 are used depending on the model bird or mammal being considered. For superlipophilic chemicals, i.e., log K_{ow} greater than 6.5, chemical-specific information should be used to determine the appropriate FCM to use because the FCM may range from 0.1 and 100. In the absence of chemical-specific information, a FCM of one should be used.

C. Predicted BCFs Based on Octanol-Water Partition Coefficient

In the absence of acceptable measured BAFs and/or BCFs for lipophilic organic chemicals, a BAF is calculated using the relationship between the BCF and the log of the octanol-water partition coefficient. BCFs based on log K_{ow} values will be multiplied by the appropriate FCM to reflect bioaccumulation.

Professional judgment should be used to select an appropriate log K_{ow} value on the basis of the available measured and calculated values for the chemical of concern and possibly its isomers and congeners.

A BCF is calculated from the chemical's log K_{ow} using equation 1 from Veith and Kosian (1983).

$$\log BCF = 0.79 \log K_{ow} - 0.40. \quad (1)$$

Where:

$\log K_{ow}$=the log of the octanol-water partition coefficient.

Equation 1 is likely to overestimate the true BCF as log K_{ow} values increase above 6.5. For any chemical for which Equation 1 predicts a BCF of over 100,000, a BCF of 100,000 should be used.

D. BAF Calculation

1. A species mean normalized BAF or BCF is calculated if more than one measured normalized BAF or BCF is available for a given species. For each chemical, the geometric mean of one or more normalized species mean BAFs or BCFs is calculated.

2. The BAF for a chemical for which one or more field-measured BAFs are available is calculated as follows:

a. Human Health BAF=(mean normalized BAF) (5.0)

b. Wildlife BAF=(mean normalized BAF) (7.9)

Where:

5.0 and 7.9 are the standardized lipid values used to derive human health and wildlife criteria and values, respectively, for the GLI.

3. The BAF for a chemical for which one or more laboratory-measured BCFs are available is calculated as follows:

a. Human Health BAF=(mean normalized BCF) (5.0) (FCM)

b. Wildlife BAF=(mean normalized BCF)(7.9)(FCM)

Where:

5.0 and 7.9 are as described above, and FCM is the appropriate food chain multiplier from Table B–1 of this appendix.

4. A BAF for a chemical for which no measured BAF or BCF is available is calculated as follows:

a. Human Health BAF=(predicted BCF)(5.0/7.6)(FCM)

b. Wildlife BAF=(predicted BCF)(7.9/7.6)(FCM)

Where:

predicted BCF is from Equation 1, not to exceed 100,000, 5.0 and 7.9 are as described above, 7.6 is the average percent lipid of the organisms used to establish the relationship between BCF and log K_{ow}, and FCM is the appropriate food chain multiplier from Table B–1 of this appendix.

5. Both human health and wildlife BAFs should be reviewed for consistency with all available data concerning the bioaccumulation of the chemical. In particular, information on metabolism, molecular size, or other physicochemical properties which might enhance or inhibit bioaccumulation should be considered. The BAFs may be modified if changes can be justified by the data.

VII. Literature Cited

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Tables to Appendix B of Part 132

TABLE B–1.—AQUATIC FOOD CHAIN MULTIPLIERS

Log K_{ow}	Trophic Level[a]		
	2	3	4
≤3.9	1.0	1.0	1.0
4.0	1.1	1.0	1.0
4.1	1.1	1.1	1.1
4.2	1.1	1.1	1.1
4.3	1.1	1.1	1.1
4.4	1.2	1.1	1.1
4.5	1.2	1.2	1.2
4.6	1.2	1.3	1.3
4.7	1.3	1.4	1.4
4.8	1.4	1.5	1.6
4.9	1.5	1.8	2.0
5.0	1.6	2.1	2.6
5.1	1.7	2.5	3.2
5.2	1.9	3.0	4.3
5.3	2.2	3.7	5.8
5.4	2.4	4.6	8.0
5.5	2.8	5.9	11
5.6	3.3	7.5	16
5.7	3.9	9.8	23
5.8	4.6	13	33
5.9	5.6	17	47
6.0	6.8	21	67
6.1	8.2	25	75
6.2	10	29	84
6.3	13	34	92
6.4	15	39	98
6.5	19	45	100
>6.5	[b]	[b]	[b]

[a] Trophic level: 2 is zooplankton, 3 is small fish, 4 is piscivorous fish including top predators.

[b] For chemicals with log K_{ow} values greater than 6.5 the FCM can range from 0.1 to 100. Such chemicals should be evaluated individually to determine the appropriate FCM. In the absence of chemical-specific information, a FCM of 1.0 should be used.

Appendix C to Part 132—Great Lakes Water Quality Initiative Methodology for Development of Human Health Criteria and Values

I. Introduction

A. Goal

The goal of the human health criteria for the Great Lakes System is the protection of humans from unacceptable exposure to toxicants via consumption of contaminated fish and drinking water and from ingesting water as a result of participation in water-oriented recreational activities.

B. Level of Protection

The criteria developed shall provide a level of protection likely to be without appreciable risk of carcinogenic and/or non-carcinogenic effects. Criteria are a function of the level of design risk or no adverse effect estimation, selection of data and exposure assumptions. Ambient criteria for single carcinogens shall not be set at a level representing a lifetime incremental risk greater than one in 100,000 of developing cancer using the hazard assessment techniques and exposure assumptions described herein. Criteria affording protection from noncarcinogenic effects shall be established at levels that, taking into account uncertainties, are considered likely to be without an appreciable risk of adverse human health effects (i.e., acute, subchronic and chronic toxicity including reproductive and developmental effects) during a lifetime of exposure, using the risk assessment techniques and exposure assumptions described herein.

C. Two-tiered Classification

Chemical concentration levels in surface water protective of human health shall be derived based on either a Tier I or Tier II classification. The two Tiers are primarily distinguished by the amount of toxicity data available for deriving the concentration levels.

II. Minimum Data Requirements

The best available toxicity data on the adverse health effects of a chemical shall be used when developing Tier I criteria or Tier II values. The best available toxicity data shall include data from well conducted epidemiologic and/or animal studies which provide (in the case of carcinogens) an adequate weight of evidence of potential human carcinogenicity and, in the case of non-carcinogens, a dose response relationship involving critical effects biologically relevant to humans. Such information should be obtained from the EPA Integrated Risk Information System (IRIS) database, the scientific literature, and other informational databases, studies and/or reports containing adverse health effects data of adequate quality for use in this procedure. Strong consideration shall be given to the most currently available guidance provided by IRIS in deriving criteria or values, supplemented with any recent data not incorporated into IRIS.

A. Carcinogens

Tier I criteria and Tier II values will be derived pursuant to section III.A of this appendix when there is adequate evidence of potential human carcinogenic effects for a chemical. It is strongly recommended that the EPA classification system for chemical carcinogens, which is described in the 1986 EPA Guidelines for Carcinogenic Risk Assessment (U.S. EPA, 1986), or future modifications thereto, be used in determining whether adequate evidence of potential carcinogenic effects exists.

1. *Tier I:* Weight of evidence of potential human carcinogenic effects sufficient to derive a Tier I human cancer criterion shall generally include human carcinogens, and probable human carcinogens. Chemicals are described as human carcinogens when there is sufficient evidence from epidemiological studies to support a causal association between exposure to the agents and cancer. Chemicals described as probable human carcinogens include agents for which the weight of evidence of human carcinogenicity based on epidemiological studies is limited. Probable human carcinogens are also agents for which there is sufficient evidence from animal studies and for which there is inadequate evidence or no data from epidemiologic studies. Possible human carcinogens, may be suitable for Tier I criterion development where studies have been well-conducted albeit are limited, when compared to studies used in classifying human and probable human carcinogens, because they involve only a single species, strain or experiment which does not demonstrate a high incidence, unusual site or type of tumor, or early onset. Possible human carcinogens are agents with limited evidence of carcinogenicity in animals in the absence of human data. Limited evidence includes a wide variety of evidence, e.g., (a) a malignant tumor response in a single well-conducted experiment that does not meet conditions for sufficient evidence, (b) tumor response of marginal statistical significance in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) response of marginal statistical significance in a tissue known to have a high or variable background rate.

a. The weight of evidence for carcinogenicity from studies in humans is classified as:

i. Sufficient when the evidence indicates that there is a causal relationship between the agent and human cancer.

ii. Limited when the evidence indicates that a causal interpretation is credible, but that alternative explanations, such as chance, bias, or confounding, could not adequately be excluded.

iii. Inadequate when the evidence indicates that one of two conditions prevailed:

(a) There were few pertinent data, or

(b) The available studies, while showing evidence of association, did not exclude chance, bias, or confounding and therefore a causal interpretation is not credible.

b. The weight of evidence for carcinogenicity from studies in experimental animals is classified as:

i. Sufficient when the evidence indicates that there is an increased incidence of malignant tumors or combined malignant and benign tumors:

(a) In multiple species or strains;

(b) In multiple experiments (e.g., with different routes of administration or using different dose levels); or

(c) To an unusual degree in a single experiment with regard to high incidence, unusual site or type of tumor, or early age at onset.

Additional evidence may be provided by data on dose-response effects, as well as information from short-term tests or on chemical structure.

ii. Limited when the data suggest a carcinogenic effect but are limited because:

(a) The studies involve a single species, strain, or experiment and do not meet criteria for sufficient evidence (see preceding paragraph); or

(b) The experiments are restricted by inadequate dosage levels, inadequate duration of exposure to the agent, inadequate period of follow-up, poor survival, too few animals, or inadequate reporting; or

(c) The studies indicate an increase in the incidence of benign tumors only.

iii. Inadequate when, because of major qualitative or quantitative limitations, the evidence cannot be interpreted as showing either the presence or absence of a carcinogenic effect.

2. *Tier II:* Weight-of-evidence of possible human carcinogenic effects sufficient to derive a Tier II human cancer value shall include those possible human carcinogens, with data sufficient for quantitative risk assessment, however inadequate for Tier I criterion development due to a tumor response of marginal statistical significance or inability to derive a strong dose-response relationship.

B. Noncarcinogens

All available toxicity data shall be evaluated considering the full range of possible health effects of a chemical, i.e., acute/subacute, chronic/subchronic and reproductive/developmental effects, in order to best describe the dose-response relationship of the chemical, and to calculate human noncancer criteria and values data which will protect against the most sensitive endpoint(s) of toxicity. Although it is desirable to have an extensive database which considers a wide range of possible adverse effects, this type of data exists for a very limited number of chemicals. For many others, there is a range in quality and quantity of data available. To assure minimum reliability of criteria and values, it is necessary to establish a minimum database below which development of criteria or values cannot proceed. The following, although not ideal, represent the minimum data sets necessary for this procedure.

1. *Tier I:* The minimum data sufficient to derive a Tier I human criterion shall include at least one well-conducted epidemiologic study or animal study. A well-conducted epidemiologic study for a Tier I human noncancer criterion must quantify exposure level(s) and demonstrate positive association between exposure to a chemical and adverse effect(s) in humans. A well-conducted study in animals must demonstrate a dose response relationship involving one or more critical effect(s) biologically relevant to humans. (For example, study results from an animal whose pharmacokinetics and toxicokinetics match those of a human would be considered most biologically relevant.) Ideally, the duration of a study should span multiple generations of exposed test species or at least a major portion of the lifespan of one generation. This type of data is currently very limited. By the use of uncertainty adjustments, shorter term studies (such as 90-day subchronic studies) with evaluation of more limited effect(s) may be used to extrapolate to longer exposures or to account for a variety of adverse effects. For Tier I criteria developed pursuant to this procedure, such a limited study must be conducted for at least 90 days in rodents or 10 percent of the lifespan of other appropriate test species and demonstrate a no observable adverse effect level (NOAEL). Chronic studies of one year or longer in rodents or 50 percent of the lifespan or greater in other appropriate test species that demonstrate a lowest observable adverse effect level (LOAEL) may be sufficient for use in Tier I criterion derivation if the effects observed at the LOAEL were relatively mild and reversible as compared to effects at higher doses. This does not preclude the use of a LOAEL from a study with only one or two doses if the effects observed appear minimal when compared to effect levels observed at higher doses in other studies.

2. *Tier II:* When sufficient data are not available to meet the Tier I data requirements, a more limited database may be considered for Tier II values development. As with Tier I, all available data shall be considered and ideally should address a range of adverse health effects with exposure over a substantial portion of the lifespan (or multiple generations) of the test species. When such data are lacking it may be necessary to rely on less than ideal data in order to establish a Tier II value. With the use of appropriate uncertainty factors to account for such limited data, the minimum data sufficient to derive a Tier II value shall include a NOAEL from at least one well-conducted short-term repeated dose study. This study shall be of at least 28 days duration, in animals demonstrating a dose-response, and involving effects biologically relevant to humans. Data from studies of longer duration (greater than 28 days) and LOAELs from such studies may be more appropriate in some cases for derivation of Tier II values. Use of a particular LOAEL should be based on consideration of the following information: severity of effect, quality of the study and duration of the study. An additional uncertainty factor may be applied to a LOAEL or NOAEL in addition to the standard uncertainty factors which account for intra- and interspecies variability (and for a lack of an identifiable NOAEL when a LOAEL is used), in order to further accommodate the extrapolation of short study duration (28 days) to lifetime exposure and to compensate for the lack of a complete toxicological data base. Structure-activity relationships (SAR) may be used along with all other data available on a chemical to determine the appropriate additional uncertainty factor to be used with such limited data.

III. Principles for Development of Tier I Criteria or Tier II Values

The fundamental components of the procedure to calculate Tier I criteria or Tier II values are the same. However, certain of the aspects of the procedure designed to account for short-duration studies or other limitations in data are more likely to be relevant in deriving Tier II values than Tier I criteria.

A. Carcinogens

1. A non-threshold mechanism of carcinogenesis shall be assumed unless biological data adequately demonstrate the existence of a threshold on a chemical-specific basis.

2. All appropriate human epidemiologic data and animal cancer bioassay data shall be considered. Data specific to an environmentally appropriate route of exposure shall be used. Oral exposure should be used preferentially over dermal and inhalation. The risk associated dose shall be set at a level corresponding to an incremental cancer risk of one in 100,000. If acceptable human epidemiologic data are available for a chemical, it shall be used to derive the risk associated dose. If acceptable human epidemiologic data are not available, the risk associated dose shall be derived from available animal bioassay data. Data from a species that responds most like humans is preferred where all other considerations regarding quality of data are equal. For example, in the absence of data to distinguish the most relevant species, data from the most sensitive species tested, i.e., the species showing a carcinogenic effect at the lowest administered dose, shall generally be used.

3. When animal bioassay data are used and a non-threshold mechanism of carcinogenicity is assumed, the data are fitted to a linearized multistage computer model (e.g, Global '86 or equivalent model). Global '86 is the linearized multistage model, derived by Howe, Crump and Van Landingham (1986) which EPA uses to determine cancer potencies. The upper-bound 95 percent confidence limit on risk (or, the lower 95 percent confidence limit on dose) at the one in 100,000 risk level shall be used to calculate a risk associated dose (RAD). Other models, including modifications or variations of the linear multistage model which consider the data more appropriately may be used on a case-by-case basis.

4. If the duration of experiment is significantly less than the natural lifespan of the test animal (for example, as cited in the Human Health TSD, 78 weeks for mice and 90 weeks for rats), the slope will be adjusted to compensate for latent tumors which were not expressed (see, e.g., U.S. EPA, 1980.)

5. A species scaling factor shall be used to account for differences between test species and humans. It shall be assumed that milligrams per surface area per day is an equivalent dose between species (U.S. EPA, 1986). All doses presented in mg/kg bodyweight will be converted to an equivalent surface area dose by raising the mg/kg dose to the ⅔ power. However, if adequate pharmacokinetic and metabolism studies are available, these data may be factored into the adjustment for species differences on a case-by-case basis.

6. Additional data selection and adjustment decisions must also be made in the process of quantifying risk. Consideration must be given to tumor selection for modeling, e.g., pooling estimates for multiple tumor types and identifying and combining benign and malignant tumors. All doses shall be adjusted to give an average daily dose over the study duration. Adjustments in the rate of tumor response must be made for early mortality in test species. The goodness-of-fit of the model to the data must also be assessed.

7. When a linear, non-threshold dose response relationship is assumed, the risk associated dose shall be calculated using the following equation:

$$RAD = \frac{0.00001}{q_1^*}$$

Where:

RAD = risk associated dose in milligrams of toxicant per kilogram body weight per day (mg/kg/day).

0.00001 (1×10^{-5}) = incremental risk of developing cancer equal to one in 100,000.

q_1^* = slope factor $(mg/kg/day)^{-1}$.

8. If human epidemiologic data and/or other biological data (animal) indicate that a chemical causes cancer via a threshold mechanism, the risk associated dose may be calculated via a method which assumes a threshold mechanism is operative on a case-by-case basis.

B. Noncarcinogens

1. Noncarcinogens shall generally be assumed to have a threshold dose or concentration below which no adverse effects should be observed. Therefore, the Tier I criterion or Tier II value is the maximum water concentration of a substance at or below which a lifetime exposure from drinking the water, consuming fish caught in the water, and ingesting water as a result of participating in water-related recreation activities is likely to be without appreciable risk of deleterious effects.

For some noncarcinogens, there may not be a threshold dose below which no adverse effects should be observed. Chemicals acting as genotoxic teratogens and germline mutagens are thought to possibly produce reproductive and/or developmental effects via a genetically linked mechanism which may have no threshold. Other chemicals also may not demonstrate a threshold. Criteria for these types of chemicals will be established on a case-by-case basis using appropriate assumptions reflecting the likelihood that no threshold exists.

2. All appropriate human and animal toxicologic data shall be reviewed and evaluated. Exposure should be via a route most relevant to environmental exposure. When acceptable human data are not available (e.g., well-conducted epidemiologic studies), animal data from species most biologically relevant to humans shall be used. In the absence of data to distinguish the most relevant species, data from the most sensitive animal species tested, i.e., the species showing a toxic effect at the lowest administered dose (given a relevant route of exposure), shall generally be used.

3. Minimum data requirements are specified in section II.B of this appendix. The experimental exposure level representing the highest level tested at which no adverse effects were demonstrated (NOAEL) from studies satisfying the provisions of section II.B of this appendix shall be used for criteria calculations. In the absence of a NOAEL, the lowest observable adverse effect level (LOAEL) from studies satisfying the provisions of section II.B of this appendix may be used if it is based on relatively mild and reversible effects.

4. Uncertainty factors shall be used to account for the uncertainties in predicting acceptable dose levels for the general human population based upon experimental animal data or limited human data.

a. An uncertainty factor of 10 shall generally be used when extrapolating from valid experimental results from studies on prolonged exposure to average healthy humans. This 10-fold factor is used to protect sensitive members of the human population.

b. An uncertainty factor of 100 shall generally be used when extrapolating from valid results of long-term studies on experimental animals when results of studies of human exposure are not available or are inadequate. In comparison to a, above, this represents an additional 10-fold uncertainty factor in extrapolating data from the average animal to the average human.

c. An uncertainty factor of up to 1000 shall generally be used when extrapolating from animal studies for which the exposure duration is less than chronic or when other significant deficiencies in study quality are present, and when useful long-term human data are not available. In comparison to b, above, this represents an additional uncertainty factor of up to 10-fold. The level of additional uncertainty applied for subchronic exposure depends on the duration of the study used relative to the lifetime of the experimental animal.

d. An additional uncertainty factor of between one and ten may be used when deriving a criterion from a lowest observable adverse effect level (LOAEL). This uncertainty factor accounts for the lack of an identifiable no observable adverse effect level (NOAEL). The level of additional uncertainty applied may depend upon the severity of the observed adverse effect.

e. An additional uncertainty factor of between one and ten may be applied when there are limited effects data or incomplete subacute or chronic toxicity data. The level of quality and quantity of the experimental data available as well as structure-activity relationships may be used to determine the factor selected.

f. When deriving an uncertainty factor in developing a Tier I criterion or Tier II value, the total uncertainty, as calculated following the guidance of 4.a–e, cited above, shall not exceed 30,000.

5. All study results shall be converted, as necessary, to the standard unit for acceptable daily exposure of milligrams of toxicant per kilogram of body weight per day (mg/kg/day). Doses will be adjusted for continuous exposure, i.e., seven days/week, 24 hours/day, etc.

C. Criteria and Value Derivation

1. *Standard Exposure Assumptions.* The following represent the standard exposure assumptions used to calculate Tier I criteria and Tier II values for carcinogens and noncarcinogens. Higher levels of exposure may be assumed by States and Tribes pursuant to CWA section 510, or where appropriate in deriving site-specific criteria pursuant to procedure 1 in appendix F to part 132.

Wh = weight of an average human (Wh = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

or

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015 kg/day.

BAF = bioaccumulation factor, as derived using the BAF methodology in appendix B to part 132.

2. *Carcinogens.* The Tier I human cancer criteria or Tier II values shall be calculated as follows:

$$HCV = \frac{RAD \times Wh}{WC + (FC \times BAF)}$$

Where:

HCV = Human Cancer Value in milligrams per liter (mg/L).

RAD = Risk associated dose in milligrams toxicant per kilogram body weight per day (mg/kg/day) that is associated with a lifetime incremental cancer risk equal to one in 100,000.

Wh = weight of an average human (Wh = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

or

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015 kg/day.

BAF = bioaccumulation factor, as derived using the BAF methodology in appendix B to part 132.

3. *Noncarcinogens.* The Tier I human noncancer criteria or Tier II values shall be calculated as follows:

$$HNV = \frac{ADE \times Wh \times RSC}{WC + (FC \times BAF)}$$

Where:

HNV = Human noncancer value in milligrams per liter (mg/L).

ADE = Acceptable daily exposure in milligrams toxicant per kilogram body weight per day (mg/kg/day).

RSC = Relative source contribution factor of 0.8 for bioaccumulative chemicals of concern. This shall be applied to bioaccumulative chemicals of concern.

Wh = weight of an average human (Wh = 70kg).

WC_d = per capita water consumption (both drinking and incidental exposure) for surface waters classified as public water supplies = two liters/day.

or

WC_r = per capita incidental daily water ingestion for surface waters not used as human drinking water sources = 0.01 liters/day.

FC = per capita daily consumption of regionally caught freshwater fish = 0.015 kg/day.

BAF = bioaccumulation factor, as derived using the BAF methodology in appendix B to part 132.

IV. References

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Appendix D to Part 132—Great Lakes Water Quality Initiative Methodology for the Development of Wildlife Criteria and Values

I. Introduction

A Great Lakes Water Quality Wildlife Criterion (GLWC) is the concentration of a substance which, if not exceeded, protects avian and mammalian wildlife populations inhabiting the Great Lakes basin from adverse effects resulting from the ingestion of surface waters and aquatic prey taken from surface waters of the Great Lakes System. These criteria are numeric or narrative in nature and are based on existing toxicological studies of the substance of concern and quantitative information about the exposure of wildlife species to the substance (i.e., food and water consumption rates). Since toxicological and exposure data for individual wildlife species is limited, a GLWC is derived using a methodology similar to that used to derive noncancer human health criteria (Barnes and Dourson, 1988; NAS, 1977; NAS, 1980; U.S. EPA. 1980). Separate avian and mammalian values are developed using taxonomic class-specific toxicity data and exposure data for five representative Great Lakes basin wildlife species. The representative wildlife species selected are representative of avian and mammalian species resident in the Great Lakes basin which are likely to experience significant exposure to contaminants through the aquatic food web; they are the bald eagle, osprey, belted kingfisher, mink, and river otter. Taxonomic class-specific avian and mammalian Wildlife Values (WVs)—concentrations of a substance which if not exceeded should protect the wildlife species—are calculated using the geometric means of the species' WVs and the lower of the mammalian and avian WVs is selected as the GLWC.

This appendix establishes a two-tiered approach to the protection of avian and mammalian communities in the Great Lakes basin. This appendix sets forth the method for deriving both Tier I criteria and Tier II values.

II. Calculation of Wildlife Values for Tier I Criteria and Tier II Value Development

Table 4 of part 132 and Table D–1 of this appendix to part 132 contain the proposed Tier I criteria calculated by EPA pursuant to the provisions below. No Tier II values have been calculated.

A. Equation for Avian and Mammalian Wildlife Values

The Tier I GLWC is the lower of the two taxonomic class-specific wildlife values. A Tier II value may be based on the wildlife value derived from a single taxonomic class. These wildlife values are calculated using the equation presented below.

$$WV = \frac{[NOAEL \times SSF] \times Wt_A}{W_A + [F_A \times BAF]}$$

Where:

WV = Wildlife value in milligrams of substance per liter (mg/L).

NOAEL = No observed adverse effect level in milligrams of substance per kilogram of body weight per day (mg/kg-d) as derived from mammalian or avian studies as described in section II.E of this document.

Wt_A = Average weight in kilograms (kg) for the representative species identified for protection or the species identified as requiring greater protection.

W_A = Average daily volume of water consumed in liters per day (L/d) by the representative species identified for protection or the species identified as requiring greater protection.

SSF = Species sensitivity factor. An extrapolation factor to account for differences in toxicity between species. Further information is provided in section III.I of this document.

F_A = Average daily amount of food consumed in kilograms per day (kg/d) by the representative species identified for protection or the species identified as requiring greater protection.

BAF = Aquatic life bioaccumulation factor for wildlife in liters per kilogram (L/kg). Chosen using guidelines for wildlife presented in appendix B to part 132, Methodology for Development of Bioaccumulation Factors.

The term "wildlife value" is used to denote any value which results from each application of the equation presented above or any averaging of such numbers. It can refer to values derived using either the Tier I or Tier II database requirements. Wildlife values calculated for the representative species are used to calculate taxonomic class-specific wildlife values. "Tier II wildlife value," or "Tier II value," is used to denote any final number derived from data meeting only the Tier II requirements and using the procedure presented in this document. "Tier I wildlife value," or Tier I value," is used to denote any final number derived from data meeting the Tier I database requirements calculated using the procedure presented in this document. "Tier I criteria" are the four wildlife criteria presented in Table 4 of part 132 and in Table D–1 of this appendix to part 132.

B. Identification of Representative Species for Protection

Piscivorous species are identified as the focus of concern for wildlife criteria development in the Great Lakes. An analysis of known or estimated exposure components for avian and mammalian wildlife species is presented in the Technical Support Document for Wildlife Criteria (U.S. EPA, 1993a). This analysis identifies three avian species and two mammalian species as representative species for protection. The NOAEL obtained from toxicity data for each taxonomic class is used to calculate Wildlife Values (WVs) for each of the five representative species identified for protection.

Because of the lack of empirical species-specific exposure information for all wildlife species in each taxonomic class, the geometric means of wildlife values for the representative species within each taxonomic class are used to determine the taxonomic class-specific wildlife value.

C. Identification of Species Requiring Greater Protection

If exposure and/or hazard data identifies a Great Lakes basin avian or mammalian wildlife species which is at risk, for which the wildlife criteria or Tier II value based on the representative species may not be adequately protective, the final avian or mammalian WV will be calculated specifically for that species. A class-specific WV for a species determined to require greater protection is calculated using the equation presented above, but using exposure information for the species determined to require greater protection. Toxicity information specific for that species is also used if it is available. This provision can be invoked in the derivation of site-specific criteria where a wildlife species has been determined to require greater protection.

D. Calculation of Avian and Mammalian Wildlife Values

The taxonomic class-specific Wildlife Values (WV) can be determined in two ways, both of which use the equation presented above. The avian WV is the geometric mean of the WVs calculated for the three representative avian species identified for protection or it is the WV calculated for an avian species determined to require greater protection. The mammalian WV is the geometric mean of the WVs calculated for the two representative mammalian species or it is the WV calculated for a mammalian species determined to require greater protection. When a WV is calculated for a species determined to require greater protection, the taxonomic class-specific WV for use in the determination of a GLWC is the lower of the WVs calculated for the given taxonomic class (the geometric mean of the WVs calculated for the representative species or the WV calculated for the species determined to require greater protection). The Tier I GLWC is set equivalent to the lower of the avian or mammalian WVs determined.

III. Parameters of the Hazard Component of the Wildlife Criteria Methodology

A. Definitions

The following definitions provide additional specificity and guidance in the evaluation of toxicity data and the application of this methodology. These definitions are applicable to both Tier I criteria and Tier II value development.

Acceptable endpoints. For the purpose of wildlife criteria derivation, acceptable subchronic and chronic endpoints are those which affect organismal growth or viability, or reproductive or developmental success or any other endpoint which is, or is directly related to, parameters that influence population dynamics.

Chronic effect. An adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure over several generations, or at least over a significant part of the test species projected life span or life stage.

Lowest-observed-adverse-effect-level (LOAEL). The lowest tested dose or concentration of a substance which resulted in an observed adverse effect in exposed test organisms when all higher doses or concentrations resulted in the same or more severe effects.

No-observed-adverse-effect-level (NOAEL). The highest tested dose or concentration of a substance which did not result in an observed adverse effect in exposed test organisms.

Subchronic effect. An adverse effect, measured by assessing an acceptable endpoint, resulting from continual exposure for a period of time less than that deemed necessary for a chronic test.

B. Minimum Toxicity Database for Tier I Criteria Development

A NOAEL or LOAEL value is required for criterion calculation. To derive a Tier I criterion for wildlife, the minimum toxicity database required must provide enough data to generate a subchronic or chronic dose-response curve for any given substance for both mammalian and avian species.

In reviewing the toxicity data available which meets the minimum data requirements for each taxonomic class, the following order of preference shall be applied to select the appropriate NOAEL or LOAEL to be used for calculation of individual wildlife values. Data from peer-reviewed field studies of wildlife species takes precedence over other types of studies. An acceptable field study must be of subchronic or chronic duration, provide a defensible, chemical-specific dose-response curve in which cause and effect are clearly established, and assess acceptable endpoints as defined in this document. When acceptable wildlife field studies are not available, the needed toxicity information may come from peer-reviewed laboratory studies. When laboratory studies are used, preference shall be given to laboratory studies with wildlife species over traditional laboratory animals to reduce uncertainties in making interspecies extrapolations. Whenever possible, all available laboratory data and field studies shall be reviewed to corroborate the final GLWC, to assess the reasonableness of the toxicity value used, and to assess the appropriateness of any uncertainty factors which are applied.

When laboratory data are used, the following requirements must be met:

1. The mammalian data must come from at least one well-conducted study of 90 days or greater designed to observe subchronic or chronic effects as defined in this document.

2. The avian data must come from at least one well-conducted study of 28 days or greater designed to observe subchronic or chronic effects as defined in this document.

In reviewing the studies from which a NOAEL is derived for use in calculating a wildlife value, studies involving exposure routes other than oral may be considered only when an equivalent oral daily dose can be estimated and technically justified. This is because the mechanism of toxicity and/or issues of dosimetry (e.g. delivered dose to target organs, extent of xenobiotic metabolism, etc.) for other routes of exposure (e.g., dermal or inhalation) may differ; and the criteria and value calculations are based on an oral route of exposure.

In assessing the studies which meet the minimum data requirements, preference should be given to studies which assess effects on developmental or reproductive endpoints because, in general, these are more important endpoints in ensuring that a population's productivity is maintained.

C. Minimum Toxicity Database for Tier II Wildlife Value Development

For those substances for which Tier I criteria cannot be derived, all data from avian and mammalian species may be considered in the development of Tier II values. To derive a Tier II value for wildlife, the minimum toxicity database required must provide enough data to generate a subchronic or chronic dose-response curve for any given substance for either a mammalian or avian species. Subchronic or chronic toxicity data shall be used to derive NOAELs for Tier II values. When laboratory data for avian species is used to calculate a Tier II wildlife value, it must meet the same requirements presented above for Tier I criteria derivation. When laboratory data for mammals is used to calculate a Tier II wildlife value, a 28-day subchronic study which assessed acceptable endpoints may be used in addition to studies which meet the requirements presented above for Tier I criteria derivation. Relevant LD50 or eight-day LC50 values from avian and mammalian studies may be used in support of subchronic and chronic toxicity data; however, a Tier II value shall not be calculated solely on the basis of LD50 or eight-day LC50 data.

D. Selection of NOAEL or LOAEL Data

In selecting data to be used in the derivation of wildlife values, the nature of the observed endpoints will be the primary selection criterion. All data not part of the selected subset may be used to assess the reasonableness of the toxicity value and the appropriateness of any uncertainty factor which is applied.

1. If more than one NOAEL is available within a taxonomic class, based on different endpoints of toxicity, that NOAEL which likely best reflects potential impacts to wildlife populations through resultant changes in mortality and/or fecundity rates shall be used for the calculation of wildlife values.

2. If more than one NOAEL is available within a taxonomic class based on the same endpoint of toxicity, the NOAEL from the most sensitive species is used.

3. If more than one NOAEL based on the same endpoint of toxicity is available for a given species, the NOAEL for that species shall be calculated using the geometric mean of those NOAELs.

E. Determination of the NOAEL in Proper Units

In those cases in which a NOAEL is available in units other than mg/kg-d, the following procedures shall be used to convert the NOAEL to appropriate units prior to calculating a wildlife value.

If the NOAEL is given in milligrams of toxicant per liter of water consumed by the test animals (mg/L), the NOAEL shall be multiplied by the daily average volume of water consumed by the test animals in liters per day (L/d) and divided by the average weight of the test animals in kilograms (kg).

If the NOAEL is given in milligrams of toxicant per kilogram of food consumed by the test animals (mg/kg), the NOAEL shall be multiplied by the average amount of food in kilograms consumed daily by the test animals (kg/d) and divided by the average weight of the test animals in kilograms (kg).

F. Drinking and Feeding Rates

When drinking and feeding rates and body weight are needed to express the NOAEL in mg/kg-d, they should be obtained from the study from which the NOAEL was derived. If not already determined, body weight, and drinking and feeding rates are to be converted to a wet weight basis.

If the study does not provide the needed values, they shall be determined from appropriate data tables for the particular study species. For studies done with domestic laboratory animals, the following reference should be consulted: Registry of Toxic Effects of Chemical Substances (National Institute for Occupational Safety and Health, the latest edition, Cincinnati, OH.). When insufficient data exist for other mammalian or avian species, the allometric equations from Calder and Braun (1983) and Nagy (1987) which are presented below shall be applied to approximate the needed feeding or drinking rates.

For mammalian species the allometric equations are:

1. $$F_A = 0.0687 \times (Wt_A)^{0.82}$$

Where:

F_A=Feeding rate of mammalian species in kilograms per day (kg/d) dry weight.

Wt_A=Average weight in kilograms (kg) of the test animals.

2. $$W_A = 0.099 \times (Wt_A)^{0.90}$$

Where:

W_A=Drinking rate of mammalian species in liters per day (L/d).

Wt_A=Average weight in kilograms (kg) of the test animals.

For avian species the allometric equations are:

3. $$F_A = 0.0582 \times (Wt_A)^{0.65}$$

Where:

F_A=Feeding rate of avian species in kilograms per day (kg/d) dry weight.

Wt_A=Average weight in kilograms (kg) of the test animals.

4. $$W_A = 0.059 \times (Wt_A)^{0.67}$$

Where:

W_A=Drinking rate of avian species in liters per day (L/d).

Wt_A=Average weight in kilograms (kg) of the test animals.

G. LOAEL to NOAEL Extrapolations

In those cases in which a NOAEL is unavailable and a LOAEL is available, the LOAEL may be adjusted to estimate the NOAEL. Typically, the LOAEL is divided by an uncertainty factor to estimate a NOAEL for use in deriving wildlife values. The value of the uncertainty factor is typically within the range of 1.0 and 10, depending on the dose-response curve. Additional references which support this concept and are useful in choosing an appropriate LOAEL to NOAEL uncertainty factor are provided in the Technical Support Document for Wildlife Criteria (U.S. EPA, 1993a). Assistance in choosing an appropriate LOAEL to NOAEL uncertainty factor is also provided in appendix A to the Great Lakes Water Quality Initiative (GLWQI) Technical Support Document for Human Health Criteria and Values (U.S. EPA, 1993b).

H. Subchronic to Chronic Extrapolations

In certain instances where only subchronic data are available, the NOAEL may be divided by an uncertainty factor to extrapolate from subchronic to chronic levels. Typically the value of the uncertainty factor is within the range of 1.0 and 10. This factor may be used when assessing highly bioaccumulative substances where toxicokinetic considerations suggest that a bioassay of limited length underestimates chronic hazard. Assistance in choosing an appropriate subchronic to chronic uncertainty factor is provided in appendix A to the GLWQI Technical Support Document for Human Health Criteria and Values (U.S. EPA, 1993b).

I. Species Sensitivity Factor

The selection of the species sensitivity factor (SSF) shall be based on the available toxicological data and on available data concerning the physicochemical, toxicokinetic and toxicodynamic properties of the substance in question and the amount and quality of available data. This value is an uncertainty factor that is intended to account for differences in toxicological sensitivity among species. Guidance for choosing the SSF is provided in the Technical Support Document for Wildlife Criteria (U.S. EPA, 1993a). The discussion of an interspecies uncertainty factor located in appendix A to the GLWQI Technical Support Document for Human Health Criteria and Values (U.S. EPA, 1993b) may also be useful in determining the appropriate value for a SSF.

For the derivation of Tier I criteria, a SSF within the range of 0.01 to 1.0 may be applied. If a SSF outside this range is used, it must be based on sound scientific and technical reasons and must be accompanied by a written justification presenting this reasoning. This justification shall be provided to EPA as part of the State's or Tribe's submission as required under § 132.5. Use of a SSF outside this range is prohibited unless approved by EPA based on its consideration of the justification provided. For Tier I wildlife criteria, the SSF shall be used for extrapolating toxicity data across species within a taxonomic class. The Tier I SSF is not intended for interclass extrapolations because of the poorly defined comparative toxicokinetic and toxicodynamic parameters between mammals and birds. However, an interclass extrapolation employing a SSF may be used for a given chemical if it can be supported by a validated biologically-based dose-response model or by an analysis of interclass toxicological data, considerate of acceptable endpoints, for a chemical analog that acts under the same mode of toxic action.

For the derivation of Tier II wildlife values, a SSF may not be greater than 1.0 but may be lower than 0.01 without requiring a written justification. For Tier II wildlife values, the SSF may be used to extrapolate toxicity data across the two taxonomic classes.

IV. Parameters of the Exposure Component of the Wildlife Criteria Methodology

A. Drinking and Feeding Rates of Representative Species or Species Requiring Greater Protection

The body weights (Wt_A), feeding rates (F_A), and drinking rates (W_A) for each of the five representative species are presented in Table D–2 of this appendix. Trophic level dietary composition for these species are also presented in Table D–2 of this appendix for use in selecting the correct bioaccumulation factor for use in the WV equation.

If the feeding rate (F_A) or drinking rate (W_A) for the species requiring greater protection are not known, they can be estimated using the allometric equations presented above in section III.F of this appendix.

B. Bioaccumulation Factors

The Methodology for Development of Bioaccumulation Factors is presented in appendix B to part 132. This Guidance document specifies that, in general, trophic level three or four BAFs are to be used in the derivation of wildlife values, depending on the species identified for protection. Trophic level three and four BAFs are used because these are the trophic levels at which the representative species identified for protection feed. Options to use plant and or other trophic level BAFs are permitted based on the identification of a species requiring greater protection which may feed, in part or whole, at other trophic levels.

V. References

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Tables to Appendix D to Part 132

TABLE D–1.—TIER I GREAT LAKES WILDLIFE CRITERIA

Substance	Criterion
DDT & Metabolites	0.87 pg/L
Mercury	180 pg/L
PCBs (total)	17 pg/L
2,3,7,8-TCDD	0.0096 pg/L

TABLE D–2.—EXPOSURE PARAMETERS FOR THE FIVE REPRESENTATIVE SPECIES IDENTIFIED FOR PROTECTION

Species	Body Wt. (Wt_A) (Kg)	Ingestion rate (F_A) (Kg/d)	Drinking rate (W_A) (L/d)	Trophic level of wildlife food source	Percent diet at each trophic level
Mink	1.0	0.15	0.099	3	100
Otter	8.0	0.9	0.64	3	50
	.....	.....	.....	4	50
Kingfisher	0.15	0.075	0.017	3	100
Osprey	1.5	0.3	0.077	3	100
Eagle	4.5	0.5	0.16	4	100

Appendix E to Part 132—Great Lakes Water Quality Initiative Antidegradation Policy

I. Antidegradation Standard

This antidegradation standard shall be applicable to any source, point or nonpoint, of pollutants to surface waters of the Great Lakes System. Pursuant to this standard:

A. Existing instream water uses, as defined pursuant to 40 CFR part 131, and the level of water quality necessary to protect existing uses shall be maintained and protected. Where designated uses of the water body are impaired, there shall be no lowering of the water quality with respect to the pollutant or pollutants which are causing the impairment;

B. Where, for any parameter, the water quality exceeds that level necessary to support the propagation of fish, shellfish, and wildlife and recreation in and on the waters, that water shall be considered high quality for that parameter and that quality shall be maintained and protected unless the State finds, after full satisfaction of intergovernmental coordination and public participation provisions of the State's continuing planning process, that allowing lower water quality is necessary to accommodate important economic or social development in the area in which the waters are located. In allowing such degradation, the State shall assure water quality adequate to protect existing uses fully. Further, the State shall assure that there shall be achieved the highest statutory and regulatory requirements for all new and existing point sources and all cost effective and reasonable best management practices for nonpoint source controls. The State shall utilize the Antidegradation Implementation Procedures of section II of this appendix, the Antidegradation Demonstration provisions of section III of this appendix, and the Antidegradation Decision provisions of section IV of this appendix in determining if the significant lowering of water quality shall be allowed;

C. Where high quality waters constitute an outstanding National resource, such as waters of National and State parks and wildlife refuges and waters of exceptional recreational or ecological significance, that water quality shall be maintained and protected; and

D. In those cases where the potential lowering of water quality is associated with a thermal discharge, the decision to allow such degradation shall be consistent with section 316 of the Clean Water Act.

II. Antidegradation Implementation Procedures

A. *Definitions—Bioaccumulative chemical of concern.* A bioaccumulative chemical of concern is: Any chemical which, upon entering the surface waters, by itself or as its transformation product, bioaccumulates in aquatic organisms by a factor greater than 1000. BCCs include all of the pollutants identified as BCCs in Table 6 of part 132.

De minimis. The lowering of water quality by a pollutant may be considered de minimis if it satisfies all of the following criteria for the pollutant under consideration, and such a determination is consistent with applicable requirements and limitations in appendix F to 40 CFR 132 (implementation procedures), including appropriate margin of safety allocations:

—The lowering of water quality does not involve a bioaccumulative chemical of concern;

—The lowering of water quality uses less than 10 percent of the unused assimilative capacity; and

—For pollutants included on Table 5 of part 132, at least 10 percent of the total assimilative capacity remains unused after the lowering of water quality;

where:

—Unless impracticable, the total assimilative capacity is determined as the product of the applicable water quality criterion times the critical low flow, or designated mixing volume in the case of lakes, for the water body in the area where the water quality is proposed to be lowered, expressed as a mass loading rate. The unused assimilative capacity is that amount of the total assimilative capacity not utilized by point

source and nonpoint source discharges. The unused assimilative capacity is established at the time the request to lower water quality is considered.

High quality waters. High quality waters are those that satisfy the criteria specified in section I.B of this appendix regarding the quality of the water.

Lake Superior Basin—Outstanding National Resource Waters. Lake Superior Basin—Outstanding National Resource Waters shall be those designated as such by the State consistent with the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. The purpose of such designations shall be to prohibit new or increased discharges of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

Lake Superior bioaccumulative substances of immediate concern. A list of substances identified in the September 1991 Bi-National Program to Restore and Protect the Lake Superior Basin. They include: 2,3,7,8–TCDD; octachlorostyrene; hexachlorobenzene; chlordane; DDT, DDE, and other metabolites; toxaphene; PCBs; and mercury. Other chemicals may be added to the list following the State's assessments of environmental effects and impacts and after public review and comment.

Outstanding National Resource Waters. Outstanding National Resource Waters (ONRWs) shall be those designated as such by the States. The State ONRW designation shall describe the quality of such waters to serve as the benchmark of the water quality that shall be maintained and protected. Categories of waters which are eligible for designation include but are not limited to the following five categories, which are waters recognized as:

—Important because of protection through official action, such as Federal or State law, Presidential or Secretarial action, international treaty, or interstate compact;
—Having exceptional recreational significance;
—Having exceptional ecological significance;
—Having other special environmental, recreational, or ecological attributes; or
—Waters whose designation as Outstanding National Resource Waters is reasonably necessary for the protection of waters identified in above.

Pollutant. The term pollutant is as defined in section 502 of the Clean Water Act and includes toxic, conventional and nonconventional pollutants, and bioaccumulative chemicals of concern as they are defined in this section.

Significant lowering of water quality. A significant lowering of water quality occurs when any of the following conditions exist:

—There is an increase in the rate of mass loading, in excess of that defined by the existing effluent quality controls established pursuant to section II. D. 1. of this appendix, of any bioaccumulative chemical of concern to the surface water from an action by the permittee at an existing, expanding or new point source;
—There is an increase in the rate of mass loading, in excess of that defined by the existing effluent quality controls established pursuant to section II. D. 1. of this appendix, of any bioaccumulative chemical of concern to the surface water from an action by the regulated entity at an existing, expanding or new nonpoint source, where existing independent regulatory authority requires compliance with water quality standards;
—There is an increase, other than a de minimis increase, in the permit limitations governing the rate of mass loading of any pollutant that is not a bioaccumulative chemical of concern to the surface water at an existing, expanding or new point source, unless the ambient concentration of the pollutant in the affected water body, outside of a designated point source mixing zone, where applicable, will not increase. The Director may also take into consideration potential impacts on sediments and biota;
—There is an increase in the permit limitations governing the rate of mass loading of any pollutant that is not a bioaccumulative chemical of concern from a nonpoint source, where existing independent regulatory authority requires compliance with water quality standards, where such permit limitations are those authorized by the governing nonpoint source program, unless the ambient concentration of the pollutant in the affected water body, outside of a designated mixing zone, where applicable, will not increase. The Director may also take into consideration potential impacts on sediments and biota; or
—For any action, where such action is determined by the Director, on a case-by-case basis, to be significant.

B. For all waters, the Director shall ensure that the level of water quality necessary to protect existing uses is maintained. In order to achieve this requirement, and consistent with 40 CFR 131.10, water quality standards use designations must include all existing uses. Controls shall be established as necessary on point and nonpoint sources of pollutants to ensure that the criteria applicable to the designated use are achieved in the water and that any designated use of a downstream water is protected. Where water quality does not support the designated uses of a water body or ambient pollutant concentrations exceed water quality criteria applicable to that water body, the Director shall allow no lowering of water quality for the pollutant or pollutants preventing the attainment of such uses or exceeding such criteria.

C. For Outstanding National Resource Waters:

1. The Director shall ensure, through the application of appropriate controls on pollutant sources, that water quality is maintained and protected.

2. Exception. A short-term, temporary (weeks or months) lowering of water quality may be permitted by the Director.

D. For high quality waters, the Director shall ensure that no significant lowering of water quality occurs except as the action resulting in the significant lowering of water quality satisfies the conditions of section III of this appendix regarding completion of an antidegradation demonstration and the information thus provided is determined by the Director pursuant to section IV of this appendix to adequately support the significant lowering of water quality.

1. To prevent the significant lowering of water quality that would result from any increased rate of mass loading of a bioaccumulative chemical of concern from any source, the Director shall establish conditions in the control document applicable to the pollutant source that restricts, unless prior approval for an increase is received from the Director, the rate of mass loading of such bioaccumulative chemical of concern to the baseline level established, considering historical rates of discharge, at the time of issuance of the control document. In establishing the existing effluent quality level, all data collected over the term of the previous control document that are representative of (a) the typical operation of the pollutant source at the time of permit issuance and (b) bioaccumulative chemical of concern mass loading rates at the time of permit reissuance, should be utilized to define the existing effluent quality. The Director may account for recent temporary changes in effluent quality that are not representative of mass loading rates generally experienced and expected to resume in the future.

For point source dischargers, such control requirements shall be specified in the discharger's National Pollutant Discharge Elimination System (NPDES) permit upon reissuance and may include, but are not limited to, effluent limitations, notification requirements, or discharge prohibitions, provided that the control requirements utilized prevent any increase in the rate of bioaccumulative chemical of concern mass loading. A subsequent increase in the rate of mass loading may be authorized by the Director provided such increase has been supported by a satisfactory antidegradation demonstration pursuant to section III of this appendix, and provided the control document is modified to specify the newly approved rate of mass loading. Control documents shall also contain a condition which prohibits the entity responsible for the pollutant loading from undertaking any deliberate action the result of which would be an increase in the rate of mass loading of any bioaccumulative chemical of concern, unless an antidegradation demonstration is provided to the Director and prior approval is obtained from the Director.

2. To prevent the significant lowering of water quality that may result from a change in control requirements, such as effluent limitations in an NPDES permit, except as such change is determined by the Director to result in a de minimis lowering of water quality based on the criteria in section II.A of this appendix, no such change shall be allowed unless and until an antidegradation demonstration pursuant to section III of this appendix is provided by the entity and approved by the Director. In addition to the above requirements, no limitation in an NPDES permit may be made less stringent in a subsequently issued permit except as in compliance with 40 CFR 122.44(l).

3. Fact Sheets prepared pursuant to 40 CFR 124.8 and 124.56 shall indicate when

conditions developed under sections II.D.1 or II.D.2 of this appendix are included in a permit.

E. *Special Provisions for Lake Superior.* The following conditions apply in addition to those specified in sections II.B through II.D of this appendix for waters of Lake Superior so designated.

1. A State may designate certain specified areas of the Lake Superior Basin as Lake Superior Basin—Outstanding National Resource Waters for the purpose of prohibiting the new or increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources in these areas.

2. States may designate all waters of the Lake Superior Basin as Outstanding International Resource Waters for the purpose of restricting the increased discharge of Lake Superior bioaccumulative substances of immediate concern from point sources consistent with the requirements of sections III.C and IV.A.3 of this appendix.

F. *Exemptions.* Except as the Director may determine on a case-by-case basis that the application of these procedures is required to adequately protect water quality, or as the affected water body is an outstanding National resource water as defined in section II.A of this appendix, the procedures in this part do not apply to:

1. Short-term, temporary (weeks or months) lowering of water quality;

2. Bypasses that are not prohibited at 40 CFR 122.41(m); and

3. Response actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, as amended, or similar Federal or State authorities, undertaken to alleviate a release into the environment of hazardous substances, pollutants or contaminants which may pose an imminent and substantial danger to public health or welfare.

III. Antidegradation Demonstration

Any entity seeking to significantly lower water quality in a high quality water or create a new or increased discharge of Lake Superior bioaccumulative substances of immediate concern in a Lake Superior Outstanding International Resource Water must first, as required by sections II.D or II.E.2 of this appendix, submit an antidegradation demonstration for consideration by the Director. The antidegradation demonstration shall identify:

A. *Pollution Prevention Alternatives Analysis.* Identify any prudent and feasible pollution prevention alternatives and techniques that are available to the entity that would eliminate or significantly reduce the extent of the lowering of water quality.

1. Alternatives that must be evaluated include:

a. Substitution of bioaccumulative chemicals of concern with non-bioaccumulative and/or non-toxic substances;

b. Application of water conservation methods;

c. Waste source reductions within process streams;

d. Recycle/reuse of waste by-products, either liquid, solid, or gaseous; and

e. Manufacturing process operational changes.

2. Should such alternatives eliminate the need to significantly lower water quality, the entity shall not be required to provide the information specified in sections III.B and III.D of this appendix.

B. *Alternative or Enhanced Treatment.* Identify alternative or enhanced treatment techniques that are available to the entity that would eliminate the significant lowering of water quality. The evaluation shall define the total capital and operation costs associated with such alternative or enhanced treatment techniques as well as the total capital and operation costs associated with pollution control facilities necessary to achieve Federal effluent guidelines-based, water quality-based effluent limitations and other applicable State or Federal standards, and calculate the ratio of the former costs to the latter costs. If the ratio is less than or equal to 1.1, the entity shall not be required to provide information specified in section III.D of this appendix.

C. *Lake Superior.* If the States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, then any entity proposing a new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern to the Lake Superior Basin shall identify the best technology in process and treatment to eliminate or reduce the extent of the significant lowering of water quality. In this case, the requirements in section III.B of this appendix do not apply.

D. *Important Social or Economic Development.* Identify the social or economic developments to the area in which the waters are located that will be foregone if the significant lowering of water quality is not allowed. Developments considered must fall into one of the following categories:

1. Increase in the number of jobs;

2. Increase in personal income or wages;

3. Reduction in the unemployment rate or other social service expenses;

4. Increase in tax revenues; or

5. Provision of necessary social services.

E. *Special Provision for Remedial Actions.* Entities proposing remedial actions pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, as amended, corrective actions pursuant to the Resource Conservation and Recovery Act, as amended, or similar actions pursuant to other Federal or State environmental statutes may submit information to the Director that demonstrates that the action utilizes the most cost effective pollution prevention and treatment techniques available, and minimizes the necessary lowering of water quality, in lieu of the information required by sections III.B through III.D of this appendix.

IV. Antidegradation Decision

A. Once the Director determines that the information provided by the entity pursuant to sections III.A through III.D of this appendix is administratively complete the Director shall use the information, as follows, to determine the extent to which water quality may be lowered by the entity. Remedial actions covered by section III.E of this appendix shall be required to implement the most cost-effective pollution prevention and treatment techniques available. All other actions shall be required to implement controls as identified pursuant to sections IV.A.1 through IV.A.5 of this appendix. In no event may the decision reached under this section allow the water quality to be lowered below the minimum level required to fully support existing uses and designated uses.

1. If the information provided pursuant to section III.A of this appendix demonstrates that there exist prudent and feasible pollution prevention alternatives which significantly reduce the lowering of water quality, the Director shall require implementation of such measures as part of the authorization to significantly lower water quality or deny the significant lowering of water quality.

2. If the cost ratio defined pursuant to section III.B of this appendix is less than or equal to 1.1, then the Director shall deny the request to significantly lower water quality.

3. If States designate the waters of Lake Superior as Outstanding International Resource Waters pursuant to section II.E.2 of this appendix, any entity requesting to lower water quality in the Lake Superior Basin as a result of the new or increased discharge of any Lake Superior bioaccumulative substance of immediate concern shall be required to install and utilize the best technology in process and treatment as identified by the Director.

4. Should the requirements of section IV.A.1, IV.A.2, or IV.A.3 of this appendix not preclude the significant lowering of water quality, the Director shall consider the social or economic developments associated with the action identified pursuant to section III.D of this appendix and the environmental effects of the significant lowering of water quality. Based on this analysis, the Director shall determine if the significant lowering of water quality should be proposed to be allowed.

5. The Director may choose to defer the review in section IV.A.4 of this appendix until after the public is provided the opportunity to comment, subject to the conditions of section IV.B.2 of this appendix.

B. The tentative decision of the Director regarding the extent to which water quality may be significantly lowered shall be subject to the public participation requirements of 40 CFR part 25. To the extent that the tentative decision is embodied in the conditions of an NPDES permit, the public participation requirements may be satisfied by the public notice of the draft permit and fact sheet which discusses the antidegradation demonstration and decision regarding the significant lowering of water quality.

1. If the Director's decision is based on the analysis in section IV.A.4 of this appendix, then the public notice of the decision shall define the extent of significant lowering of water quality tentatively determined by the Director to be allowable, and the factors considered in reaching that decision.

2. If the Director chooses to defer the review as provided in section IV.A.5 of this appendix, then the Director shall tentatively determine that the significant lowering of water quality is not allowable. The public

notice shall state that a decision that is based on a review of the social or economic developments and environmental effects associated with the action, has been deferred, pending review of the comments received from the public, and that the tentative decision may subsequently be revised.

Appendix F to Part 132—Great Lakes Water Quality Initiative Implementation Procedures

[Note: For ease of reference, sections in this appendix may be referred to by appending the section designation to the procedure number. For example, section A.1 of procedure 1 may be referred to as procedure 1.A.1 of appendix F.]

Procedure 1: Site-specific Modifications to Criteria/Values

A. *Requirements for Site-specific Modifications to Criteria/Values.* Criteria or values may be modified on a site-specific basis to reflect local environmental conditions as restricted by the following provisions. Any such modifications must be: protective of designated uses and aquatic life, wildlife and human health; and submitted to EPA for approval/disapproval. In addition, any site-specific modifications that result in less stringent criteria must be based on sound scientific rationale.

1. *Aquatic Life.* Aquatic life criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act section 510.

a. Less stringent site-specific modifications to chronic or acute aquatic life criteria or values may be developed when:

i. The local water quality parameters such as pH, hardness, temperature, color, etc., alter the biological availability and/or toxicity of a pollutant; and/or

ii. The sensitivity of the local aquatic organisms (i.e., those that would live in the water absent man-induced pollution) differs significantly from the species actually tested in developing the criteria.

Guidance on developing site-specific criteria in these instances is provided in Chapter 4 of the U.S. EPA Water Quality Standards Handbook.

b. Less stringent modifications also may be developed to the chronic aquatic life criteria or values to reflect local physical and hydrological conditions.

2. *Wildlife.* Wildlife criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act section 510. This may be accomplished through the use of an additional uncertainty or other documented factor in the equation for the Wildlife Value.

3. *Bioaccumulation.* Bioaccumulation factors may be modified on a site-specific basis to larger values than derived pursuant to authority reserved to the States and Tribes under Clean Water Act section 510. Bioaccumulation factors shall be modified on a site-specific basis where reliable data shows that local bioaccumulation is greater than the system-wide value.

4. *Human Health.* Human health criteria or values may be modified on a site-specific basis to provide an additional level of protection, pursuant to authority reserved to the States and Tribes under Clean Water Act section 510. Human health criteria or values shall be modified on a site-specific basis to provide additional protection appropriate for highly exposed subpopulations.

B. *Notification Requirements.* When a State proposes a site-specific modification to a criterion or value as allowed in section A above, the State shall notify the other Great Lakes States of such a proposal and, for less stringent criteria, supply appropriate justification.

C. *References.* U.S. EPA. 1983. Water Quality Standards Handbook. Chapter 4. U.S. Environmental Protection Agency, Office of Water Resource Center (RC–4100), 401 M Street, SW., Washington, DC 20960.

Procedure 2: Variances from Water Quality Standards for Point Sources

The Great Lakes States or Tribes may adopt water quality standards (WQS) variance procedures and may grant WQS variances for point sources in compliance with such procedures. Any adopted variance procedures shall be at least as stringent as the provisions in this Guidance.

A. *Applicability.* The Great Lakes States or Tribes may grant a variance to a water quality standard (WQS) which is the basis of a water quality-based effluent limitation included in an NPDES permit. A WQS variance applies only to the permittee requesting the variance and only to the pollutant or pollutants specified in the variance. A variance does not affect, or require the Great Lakes States or Tribes to modify, the corresponding WQS for the water body as a whole.

This provision shall not apply to new dischargers or recommencing dischargers.

B. *Maximum Timeframe for Variances.* A WQS variance shall not exceed three years. Upon expiration of a variance, the WQS of the water body will have full force and effect on the permittee.

C. *Conditions to Grant a Variance.* A variance may be granted if the permittee demonstrates to the Great Lakes State or Tribe that attaining the WQS is not feasible because:

1. Naturally occurring pollutant concentrations prevent the attainment of the WQS;

2. Natural, ephemeral, intermittent or low flow conditions or water levels prevent the attainment of the WQS, unless these conditions may be compensated for by the discharge of sufficient volume of effluent discharges without violating State or Tribal water conservation requirements to enable WQS to be met;

3. Human-caused conditions or sources of pollution prevent the attainment of the WQS and cannot be remedied or would cause more environmental damage to correct than to leave in place;

4. Dams, diversions or other types of hydrologic modifications preclude the attainment of the WQS, and it is not feasible to restore the water body to its original condition or to operate such modification in a way that would result in the attainment of the WQS;

5. Physical conditions related to the natural features of the water body, such as the lack of a proper substrate cover, flow, depth, pools, riffles, and the like, unrelated to water quality, preclude attainment of WQS; or

6. Controls more stringent than those required by sections 301(b) and 306 of the Clean Water Act would result in substantial and widespread economic and social impact; provided that the permittee also: demonstrates that the variance requested conforms to the requirements of the State or Tribe's antidegradation procedures; and demonstrates the extent of any increased risk to human health and the environment associated with compliance with the variance compared with compliance with WQS absent the variance, and the State or Tribe concludes that any such increased risk is consistent with the protection of the public health, safety and welfare.

A WQS variance may not be granted if standards will be attained by implementing effluent limits required under sections 301(b) and 306 of the Clean Water Act and by the permittee implementing cost-effective and reasonable best management practices for nonpoint source control.

D. *Timeframe to Submit Application.* The permittee shall submit an application for a variance no later than 60 days after the regulatory authority reissues or modifies the permit. The application shall include:

1. All relevant information demonstrating that attaining the WQS is not feasible based on one or more of the conditions in sections C.1 through C.6 of this procedure; and

2. A demonstration of compliance with the general conditions in section C of this procedure.

E. *Public Notice of Preliminary Decision.* Upon receipt of a complete application for a variance, and upon making a preliminary decision regarding the variance, the Great Lakes State or Tribe shall issue a public notice of the request and preliminary decision for public comment pursuant to the regulatory authority's Administrative Procedure Act and shall notify the other Great Lakes States and Tribes of the preliminary decision.

F. *Final Decision on Variance Request.* The Great Lakes State or Tribe shall issue a final decision on the variance request within 90 days of the expiration of the public comment period as required in section E of this procedure. If all or part of the variance is approved by the State or Tribe, the decision shall specify all permit conditions needed to implement those parts of the variance so approved. Such permit conditions shall, at a minimum, require:

1. Compliance with an initial effluent limitation which, at the time the variance is granted, represents the level currently achievable by the permittee, but no less stringent than that achieved under the previous permit;

2. That reasonable progress be made toward attaining the water quality standards for the water body as a whole through appropriate conditions; and

3. Compliance with the effluent limitation in effect immediately prior to the granting of the variance upon the expiration of said variance.

The Great Lakes State or Tribe shall deny a requested variance if the permittee fails to make the demonstration required under section C of this procedure.

G. *Incorporating State or Tribal Approved Variance into Permit.* The NPDES permitting authority shall initiate a permit modification to establish and incorporate into the permittee's NPDES permit all conditions needed to implement the variance as determined in section F of this procedure.

H. *Renewal of Variance.* A variance may be renewed, subject to the requirements of sections A through G of this procedure, except that renewal application shall be submitted no later than the required submission of a permit application for a NPDES permit, or 60 days prior to the expiration of the variance, whichever occurs earliest. As part of any renewal application, the permittee shall again have the burden of demonstrating that attaining WQS is not feasible based on the requirements of section C of this procedure. The permittee's application shall also contain information concerning its compliance with the conditions incorporated into its permit as part of the variance pursuant to section G of this procedure. A variance shall not be renewed if the permittee did not comply with the conditions of the variance.

I. *EPA Approval.* All variances, including:

1. Relevant permittee applications pursuant to section D of this procedure;

2. Public comments and public hearing record pursuant to section E of this procedure;

3. Approvals pursuant to section F of this procedure; and

4. NPDES permits issued pursuant to section G of this procedure shall be submitted by the State or Tribe to the appropriate EPA Regional office.

Items required by sections I.1 through 3 of this procedure shall be submitted by the Great Lakes State or Tribe within 30 days of the date of the final variance decision. Items required by section I.4 of this procedure shall be submitted in accordance with the State or Tribal Memorandum of Agreement with the Regional Administrator pursuant to 40 CFR 123.24.

EPA shall review the State or Tribe submittal for compliance with the CWA pursuant to 40 CFR 123.44, and 40 CFR 131.21.

J. *WQS Revisions.* All variances must be appended to the State or Tribal WQS rules.

Procedure 3A: Total Maximum Daily Loads, Wasteload Allocations and Load Allocations for Point and Nonpoint Sources; (Option A)

A. *General Conditions of Application.* The following are conditions applicable to establishing total maximum daily loads (TMDLs) for all pollutants and waters within the Great Lakes System subject to the exceptions included in 40 CFR 132.4.

1. *TMDLs Required.* TMDLs shall, at a minimum, be established for each pollutant for which it is determined pursuant to procedure 5 of this appendix that there is a reasonable potential that a discharge will cause or contribute to an exceedance of water quality standards, and in advance of issuance of any new or revised permit for the discharge of such pollutant, unless it is determined pursuant to these procedures that a TMDL is not needed.

2. *Load Reductions.* TMDLs shall also be prepared if the sum of existing point source and nonpoint source (including natural background) loadings exceeds the loading capacity minus any specified margin of safety for a substance. A TMDL must ensure attainment of all numeric and narrative criteria and Tier II values for a given pollutant. TMDLs shall include WLAs for point sources and LAs for nonpoint sources such that their sum is not greater than the loading capacity minus the sum of any specified MOS and reserve capacity for future growth.

3. *WLA Values.* Point sources must be regulated so as to ensure attainment of all downstream water quality standards. If separate TMDLs are prepared for the same pollutant in different segments of the same drainage basin, and the separate TMDLs each include WLAs for one or more of the same point sources, then WQBELS shall be consistent with the most stringent WLA in an EPA approved or EPA established TMDL.

4. *Margin of Safety (MOS).* Each TMDL shall include a MOS sufficient to account for uncertainties in establishing the TMDL and describe the manner in which a MOS is provided. The MOS may be provided by leaving a portion of the loading capacity unallocated or by use of protective modeling assumptions to account for the uncertainties in deriving the TMDL. If a separate allocation of loading capacity is set aside to provide a MOS, the amount of such allocation shall be described. If protective modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

5. *More Stringent Requirements.* States may exercise authority reserved to them under section 510 of the Clean Water Act to develop more stringent TMDLs (including WLAs and LAs) than are required herein, providing that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time period as a result of implementing nonpoint source controls.

6. *Accumulation in Sediments.* TMDLs shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life. TMDLs shall consider contributions to the water column from sediments inside and outside of any applicable mixing zones.

7. *Wet Weather Events.* This guidance does not provide specific procedures for wet weather events. However, some of these procedures may be deemed appropriate for such purposes on a case-by-case basis.

8. *Background Concentrations of Pollutants.* The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs and to determine reasonable potential through use of procedure 5 of this appendix. Such loadings may be accounted for in a TMDL through an allocation to a single "background" category, or through individual allocations to the various background sources.

a. *Requirements for Calculating Background.* "Background" represents all loadings that: (1) Flow from upstream waters into the specified watershed, water body or water body segment for which a TMDL is being developed, (2) enter the specified watershed, water body or water body segment through atmospheric deposition or sediment release or resuspension, or (3) occur within the watershed, water body or water body segment as a result of chemical reactions. Background concentrations shall be determined on a case-by-case basis using acceptable available data on the specified watershed, water body or water body segment, or on similar water bodies, and best professional judgement. Available data shall include available ambient water column measurements, caged fish tissue measurements, and pollutant loading data. When determining what available data are acceptable, best professional judgement should be used, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels.

b. *Calculation Requirements.* Except as provided below, the representative background concentration for a pollutant shall be established as the geometric mean of:

i. Acceptable available water column data;

ii. Water column concentrations estimated through use of acceptable available caged fish tissue data; or

iii. Acceptable available mass loading data used to estimate water column levels.

When more than one of the above three data sets exist, best professional judgement should be used to select the one data set most likely to accurately estimate background concentrations. In utilizing mass loading data, pollutant degradation and transport information may be considered.

In certain circumstances, caged fish tissue data or ambient monitoring data may be used to estimate ambient concentrations at a given upstream location, and data on mass loadings upstream may be used to adjust that value to the background level entering the water body or water body segment of concern.

For the purpose of calculating the geometric mean, data reported as below the detection level shall be assumed to be one-half of the reported detection level; data reported as above the detection level but below the quantification level shall be assumed to be the detection level plus one-half of the difference between the reported detection level and the reported quantification level. When all of the acceptable available data in a data set or category such as water column, caged fish tissue or mass loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

9. *TMDL Allocations.* Nonpoint source load allocations shall be based on: a. existing loading rates if changes in loading rates are not anticipated; b. anticipated increased loading rates; or c. anticipated lower loading rate if such lower loading rate is technically reasonable and anticipated to occur within a

reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether any expected load reductions are technically reasonable and will occur within a reasonable period of time, technical and institutional factors should be considered. These decisions are case-specific and should reflect the particular TMDL under consideration. The portion of the loading capacity not assigned to nonpoint sources, or to a MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include limitations consistent with the WLAs in EPA approved or EPA established TMDLs.

10. *Effluent Flow.* If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analyses. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. *New Source or Discharger.* TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, a new or expanded discharge cannot be permitted unless the TMDL is revised in accordance with these procedures to include a WLA for the new or expanded discharge.

B. *Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs).* Notwithstanding any other provision in these rules, the following requirements (or any more stringent requirement established in accordance with section 510 of the Clean Water Act) shall be applied in TMDLs for BCCs:

1. Up until [*insert 10 years from the effective date of the final rule*], mixing zones for BCCs may be allowed for existing dischargers pursuant to the procedures specified in sections C and D of this procedure. However, for implementation of numeric or narrative criteria and values (including, but not limited to HCC, HCV, HNV, HNC, wildlife criteria and values, and chronic aquatic criteria and values), individual WLAs for discharges to the open waters of the Great Lakes shall assume no greater dilution than one part effluent to ten parts receiving water.

2. No later than [*insert 10 years from the effective date of the final rule*], there shall be no mixing zones available to existing dischargers for BCCs. Accordingly, the WLAs for existing dischargers shall be such as are necessary to attain water quality standards for BCCs at the point of discharge. Thus, they shall be set (1) equal to the most stringent water quality criteria or values for the BCCs in question, or (2) at a more stringent level than the most stringent water quality criteria or values if necessary due to background concentrations to meet such criteria and values at the point of discharge. Permits issued within five years prior to [*insert 10 years from the effective date of the final rule*] must include a more stringent set of limitations applicable on [*insert 10 years from the effective date of the final rule*] if necessary to implement this requirement.

3. Beginning on the effective date of these procedures, there shall be no mixing zones for BCCs available to new dischargers or new sources. Accordingly, the WLAs for new dischargers shall be such as are necessary to attain water quality standards for BCCs at the point of discharge. Thus, they shall be set (1) equal to the most stringent water quality criteria or values for the BCCs in question, or (2) at a more stringent level than the most stringent water quality criteria or values if necessary due to background concentrations to meet such criteria and values at the point of discharge.

4. States may grant mixing zones beyond the dates specified in paragraphs 2 and 3 of this section, where it can be demonstrated on a case-by-case basis that failure to grant a mixing zone would preclude water conservation measures that would lead to overall load reductions in BCCs, even though higher concentrations of BCCs occur in the effluent. Such mixing zones must also be consistent with sections C and D of this procedure.

C. *Deriving TMDLs for Discharges to Lakes.* This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes.

1. Individual point source WLAs shall assume no greater dilution than one part effluent to 10 parts receiving water (containing background levels of pollutants) for implementation of numeric or narrative chronic criteria and values (including, but not limited to Tier I and Tier II HNVs, HCVs and chronic aquatic life and wildlife criteria and values), unless, subject to restrictions for BCCs in section B of this procedure, an alternative mixing zone is demonstrated as appropriate in a mixing zone study conducted pursuant to subsection 3 of this section.

2. Appropriate mixing zone assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State requirements, on a case-by-case basis by the authority establishing the TMDL.

3. Data generated by mixing zone studies conducted by any interested party shall be used to establish allocations when, in the best professional judgement of the authority establishing the TMDL, it is determined that the mixing zone study demonstrates that a dilution allowance other than those specified in or established pursuant to sections C.1 and C.2 of this procedure is appropriate for the protection of designated and existing uses, and implementation of numeric and narrative criteria and values. Mixing zone studies shall address factors identified by the authority establishing the TMDL, including, but not limited to, density or temperature stratification of the water body, dispersion of the effluent discharge relative to situations such as the location of a water supply intake and critical biological habitat areas.

4. In cases where background concentrations exceed criteria or values, WLAs shall be set equal to zero or a multiple source TMDL shall be established that ensures attainment of criteria or values and control of BCCs pursuant to section B of this procedure.

5. A separate check is made to assure that the final WLAs provide for attainment of acute aquatic life criteria and values at the boundary of any acute mixing zone allowed under State law.

D. *The Tributary Basin Mass Balance TMDL Approach.* The basin approach to developing TMDLs addresses all known sources of a pollutant in a drainage basin in a single analysis. Where it is either not required or not feasible to develop a basin-wide TMDL, the regulatory authority shall develop a TMDL for a smaller geographic unit as necessary. The TMDL analysis shall be undertaken pursuant to the following steps:

1. *Calculation of the Tributary Basin Loading Capacity.* The loading capacity is initially calculated at the furthest downstream location in the drainage basin. The maximum allowable loading consistent with the attainment of each numeric criterion or value for a given pollutant is determined by multiplying the criterion or value by the flow at the furthest downstream location in the tributary basin at the design flow condition below:

a. Harmonic mean flow for human health criteria or values.

b. 30-day, five-year low flow for wildlife criteria or values.

c. 7-day, 10-year low flow or 4-day, 3-year biologically-based low flow for chronic aquatic life criteria or values.

The lowest load is then selected as the loading capacity.

2. *Inventory of Baseline Pollutant Loads.* An inventory of pollutant loadings (including natural background) from all known sources in the tributary basin shall be constructed.

a. The inventory for point sources uses a pollutant loading baseline which should, as appropriate, be derived from:

i. The permit limit(s) of sources discharging the pollutant of concern. The limits may be technology-based limits, water quality-based limits, or a combination of both. Actual effluent flow rates are used to convert concentration-based permit limits to an estimate of mass of pollutants discharged over time.

ii. The level of treatment currently required or required pursuant to an enforceable schedule of compliance. In appropriate circumstances this could be BAT limits for industrial discharges or secondary treatment limits for POTWs.

iii. Actual loadings of a pollutant from a facility when, for example, a limitation for the pollutant is not included in the facility's permit.

b. The inventory of nonpoint source pollutant loadings includes contributions from urban runoff, agricultural runoff, groundwater contributions (including groundwater contaminated by leaching from landfill or industrial waste disposal sites), atmospheric deposition and resuspension/resolution from contaminated sediment. Measured loading rates shall be used, when available, or best estimates calculated. Estimates should be based on loadings expected after implementation of nonpoint source controls expected to occur within a reasonable time period.

3. *Environmental Fate.* The inventory of baseline loadings conducted in sections D.2

and D.7 of this procedure and the site-specific cross checks in sections D.8 and D.9 of this procedure shall be based on the assumption that a pollutant does not degrade. If, however, each of the following conditions are met, the regulatory authority may take into account degradation of a pollutant:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant will occur under the full range of environmental conditions expected to be encountered; and

b. The field studies and other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

4. *Establish the Basin Margin of Safety (MOS).* The basin margin of safety may be represented as a portion of the loading capacity which must remain unallocated to account for the uncertainties in deriving the TMDL. Identification of a MOS should reflect consideration of the baseline loading chosen to develop the inventory (e.g., permitted versus actual loads, estimated versus measured nonpoint loads) as well as uncertainties in calculating loading capacity. For example, the MOS may vary depending on the degree of uncertainty associated with predicted nonpoint source loadings. The basin MOS will be unique and specific for each tributary basin depending on the degree of uncertainty.

5. *Compare Allowable Loading with Baseline Loading.* Compare the difference of the loading capacity calculated in section D.1 of this procedure minus any specified MOS calculated in section D.4 of this procedure to the inventory baseline load calculated in section D.2 of this procedure from all sources for the pollutant of concern. If the baseline load is greater than the difference of the loading capacity minus any specified MOS, then the tributary basin is water quality-limited and a TMDL must be developed. If the baseline load is less than the difference of the loading capacity minus any specified MOS, the basin is not water quality-limited and a TMDL for the entire basin is not necessary. Whether or not a TMDL for the entire basin is required, a mass balance cross check, as described in sections D.8 and D.9 of this procedure shall be conducted in the vicinity of each source to determine if a TMDL for a segment of the basin is necessary.

6. *Identify Load Reductions Subject to Allocation.* For a water quality-limited basin, the portion of the pollutant load which must be reduced to meet water quality standards shall be equal to the baseline load minus the loading capacity adjusted by the MOS. This represents the load reduction which must be achieved through new or revised load and/or wasteload allocations in order to meet water quality standards at the downstream terminus of the basin. Additional reductions may be necessary as determined in sections D.8 and D.9 of this procedure to ensure attainment of water quality standards throughout the basin.

7. *Conduct Allocation.* The WLAs and LAs shall be established by a reasonable process for the particular basin under investigation. Examples of allocation methods include but are not limited to:

a. Reduction of all sources proportional to their current share of the baseline load.

b. Equal percent reduction.

c. Equal effluent concentrations.

d. Most efficient reductions by selected sources.

In no event shall a load allocation be set at a level which reflects an unreasonable expectation of load reductions that will be attained by a nonpoint source within a reasonable time period.

8. *Mass Balance Site-specific Chronic Allocation Cross-check.* The basin approach to the TMDL/allocation analysis initially focuses on attainment of water quality standards at the selected downstream location. It must also be determined whether standards will be met at all locations within the basin.

At each individual point source location, a site-specific cross-check shall be performed that generates a WLA for the source that is necessary to implement all water quality standards for protection from chronic effects at that location. Such cross-checks take into consideration background concentrations immediately upstream of the point source, any applicable State mixing zone policies and a margin of safety to account for uncertainties.

Permittees may be required to conduct mixing zone demonstrations in accordance with directives of the authority establishing the TMDL where the authority determines that such a demonstration is necessary to adequately conduct the basin TMDL analysis or to evaluate chronic toxicity conditions at the edge of any applicable mixing zone.

A site specific chronic cross-check is also conducted with respect to nonpoint source loadings, and may indicate that reduced loadings are necessary in the vicinity of the nonpoint source to attain water quality standards there. It may be appropriate to reduce the LA for the nonpoint source to reflect the requisite load reduction if it can reasonably be expected that such a load reduction will in fact be achieved within a reasonable time period. Otherwise, it may be necessary to reduce the WLAs of upstream point sources in order to ensure that water quality standards are attained in the vicinity of the nonpoint source. If either the LA for a nonpoint source or the WLAs for upstream point sources are reduced for this purpose, it is possible that the allocations for some sources downstream in the tributary could be increased in the final TMDL from those initially calculated in the basin analysis, depending on site-specific considerations including individual acute and chronic cross-checks.

9. *Acute Criteria Cross-check.* A separate check shall be made to assure that acute aquatic life criteria and values are met at the boundary of any applicable acute criteria mixing zone allowed under State law. If mixing zones from two or more proximate sources interact or overlap, the combined effect will be evaluated to determine if criteria and values will be met at the edge of any applicable acute criteria mixing zones.

The acute criteria cross-check shall include, but not be limited to, consideration of: (1) The expected dilution under all effluent flow and concentration conditions at design stream flow, (2) maintenance of a zone of passage for aquatic organisms and (3) protection of critical aquatic habitat.

A permittee may be required to conduct an acute criteria mixing zone demonstration in accordance with the directives of the authority establishing the TMDL where the authority determines that such a demonstration is necessary to adequately conduct the basin TMDL/allocation analysis or is necessary to evaluate acute toxicity conditions at the edge of the acute criteria mixing zone.

10. *Determine the WLA.* The more stringent of the basin WLA, the site-specific chronic WLA or site-specific acute WLA is typically applied as a WQBEL in the source's NPDES permit. However, where a more stringent WLA is established as a result of a site-specific cross check than was initially calculated using the basin-wide analysis, revision of other WLAs or LAs initially calculated under the basin approach may be appropriate to reflect the additional unallocated basin loading, depending on site-specific considerations, including other individual acute and chronic cross checks.

11. *TMDL Validation.* Where available, ambient monitoring and other relevant data should be evaluated to assess the accuracy of the mass balance basin approach. Comparison of measured versus calculated ambient concentrations (calculated from the load inventory at the furthest downstream location) can serve as a check on the accuracy of the TMDL. Such analyses could demonstrate that a full-scale kinetic model may be useful in developing a TMDL for the basin.

Procedure 3B: Total Maximum Daily Loads, Wasteload Allocations and Load Allocations for Point and Nonpoint Sources; (Option B)

A. *General Conditions of Application.* The following are conditions applicable to establishing total maximum daily loads (TMDLs) for all pollutants and waters within the Great Lakes System subject to the exceptions included in 40 CFR 132.4.

1. *TMDLs Required.* TMDLs shall, at a minimum, be established for each pollutant for which it is determined pursuant to procedure 5 of this appendix that there is a reasonable potential that a discharge will cause or contribute to an exceedance of water quality standards, and in advance of issuance of any new or revised permit for the discharge of such pollutant, unless it is determined pursuant to these procedures that a TMDL is not needed.

2. *Load Reductions.* TMDLs shall also be prepared if the sum of existing point source and nonpoint source (including natural background) loadings exceeds the loading capacity minus any specified margin of safety for a substance. A TMDL must ensure attainment of all numeric and narrative criteria and Tier II values for a given pollutant. TMDLs shall include WLAs for point sources and LAs for nonpoint sources such that their sum is not greater than the loading capacity minus the sum of any specified MOS and reserve capacity for future growth.

3. *WLA Values.* Point sources must be regulated so as to ensure attainment of all

downstream water quality standards. If separate TMDLs are prepared for the same pollutant in different segments of the same drainage basin, and the separate TMDLs each include WLAs for one or more of the same point sources, then WQBELS shall be consistent with the most stringent WLA in an EPA approved or EPA established TMDL.

4. *Margin of Safety (MOS).* Each TMDL shall include a MOS sufficient to account for uncertainties in establishing the TMDL and describe the manner in which a MOS is provided. The MOS may be provided by leaving a portion of the loading capacity unallocated or by use of protective modeling assumptions to account for the uncertainties in deriving the TMDL. If a separate allocation of loading capacity is set aside to provide a MOS, the amount of such allocation shall be described. If protective modeling assumptions are relied on to provide a MOS, the specific assumptions providing the MOS shall be identified.

5. *More Stringent Requirements.* States may exercise authority reserved to them under section 510 of the Clean Water Act to develop more stringent TMDLs (including WLAs and LAs) than are required herein, providing that all LAs in such TMDLs reflect actual nonpoint source loads or those loads that can reasonably be expected to occur within a reasonable time period as a result of implementing nonpoint source controls.

6. *Accumulation in Sediments.* TMDLs shall be sufficiently stringent so as to prevent accumulation of the pollutant of concern in sediments to levels injurious to designated or existing uses, human health, wildlife and aquatic life. TMDLs shall consider contributions to the water column from sediments inside and outside of any applicable mixing zones.

7. *Wet Weather Events.* This guidance does not provide specific procedures for wet weather events. However, some of these procedures may be deemed appropriate for such purposes on a case-by-case basis.

8. *Background Concentrations of Pollutants.* The representative background concentration of pollutants shall be established in accordance with this subsection to develop TMDLs and to determine reasonable potential through use of procedure 5 of this appendix. Such loadings may be accounted for in a TMDL through an allocation to a single "background" category, or through individual allocations to the various background sources.

a. *Requirements for Calculating Background.* "Background" represents all loadings that: (1) Flow from upstream waters into the specified watershed, water body or water body segment for which a TMDL is being developed, (2) enter the specified watershed, water body or water body segment through atmospheric deposition or sediment release or resuspension, or (3) occur within the watershed, water body or water body segment as a result of chemical reactions. Background concentrations shall be determined on a case-by-case basis using acceptable available data on the specified watershed, water body or water body segment, or on similar water bodies, and best professional judgement. Available data shall include available ambient water column measurements, caged fish tissue measurements, and pollutant loading data. When determining what available data are acceptable, best professional judgement should be used, including consideration of the sampling location and the reliability of the data through comparison to reported analytical detection levels and quantification levels.

b. *Calculation Requirements.* Except as provided below, the representative background concentration for a pollutant shall be established as the geometric mean of:

i. Acceptable available water column data;

ii. Water column concentrations estimated through use of acceptable available caged fish tissue data; or

iii. Acceptable available mass loading data used to estimate water column levels.

When more than one of the above three data sets exist, best professional judgement should be used to select the one data set most likely to accurately estimate background concentrations. In utilizing mass loading data, pollutant degradation and transport information may be considered.

In certain circumstances, caged fish tissue data or ambient monitoring data may be used to estimate ambient concentrations at a given upstream location, and data on mass loadings upstream may be used to adjust that value to the background level entering the water body or water body segment of concern.

For the purpose of calculating the geometric mean, data reported as below the detection level shall be assumed to be one-half of the reported detection level; data reported as above the detection level but below the quantification level shall be assumed to be the detection level plus one-half of the difference between the reported detection level and the reported quantification level. When all of the acceptable available data in a data set or category such as water column, caged fish tissue or mass loading data, are below the level of detection for a pollutant, then all the data for that pollutant in that data set shall be assumed to be zero.

9. *TMDL Allocations.* Nonpoint source load allocations shall be based on: a. existing loading rates if changes in loading rates are not anticipated; b. anticipated increased loading rates; or c. anticipated lower loading rate if such lower loading rate is technically reasonably and anticipated to occur within a reasonable time period as a result of implementation of best management practices or other load reduction measures. In determining whether any expected load reductions are technically reasonable and will occur within a reasonable period of time, technical and institutional factors should be considered. These decisions are case-specific and should reflect the particular TMDL under consideration. The portion of the loading capacity not assigned to nonpoint sources, or to a MOS, or reserved for future growth is allocated to point sources. Upon reissuance, NPDES permits for these point sources must include limitations consistent with the WLAs in EPA approved or EPA established TMDLs.

10. *Effluent Flow.* If WLAs are expressed as concentrations of pollutants, the TMDL shall also indicate the point source effluent flows assumed in the analysis. Mass loading limitations established in NPDES permits must be consistent with both the WLA and assumed effluent flows used in establishing the TMDL.

11. *New Source or Discharger.* TMDLs may include reserved allocations of loading capacity to accommodate future growth and additional sources. Where such reserved allocations are not included in a TMDL, a new or expanded discharge cannot be permitted unless the TMDL is revised in accordance with these procedures to include a WLA for the new or expanded discharge.

B. *Mixing Zones for Bioaccumulative Chemicals of Concern (BCCs).* Notwithstanding any other provision in these rules, the following requirements (or any more stringent requirement established in accordance with section 510 of the Clean Water Act) shall be applied in TMDLs for BCCs:

1. Up until *[insert 10 years from the effective date of the final rule]*, mixing zones for BCCs may be allowed for existing dischargers pursuant to the procedures specified in sections C and D of this procedure. However, for implementation of numeric or narrative criteria and values including, but not limited to HCC, HCV, HNV, HNC, wildlife criteria and values, and chronic aquatic life criteria and values, individual WLAs for discharges to open waters of the Great Lakes shall assume no greater dilution than one part effluent to ten parts receiving water, and for discharges to Great Lakes System tributaries shall assume no greater dilution than that allowed under section D.3.c.iii of this procedure.

2. No later than *[insert 10 years from the effective date of the final rule]*, there shall be no mixing zones available to existing dischargers for BCCs. Accordingly, the WLAs for existing dischargers shall be such as are necessary to attain water quality standards for BCCs at the point of discharge. Thus, they shall be set (1) equal to the most stringent water quality criteria or values for the BCCs in question, or (2) at a more stringent level than the most stringent water quality criteria or values if necessary due to background concentrations to meet such criteria and values at the point of discharge. Permits issued within five years prior to *[insert 10 years from the effective date of the final rule]* must include a more stringent set of limitations applicable on *[insert 10 years from the effective date of the final rule]* if necessary to implement this requirement.

3. Beginning on *[insert the effective date of the final rule]*, there shall be no mixing zones for BCCs available to new dischargers or new sources. Accordingly, the WLAs for new dischargers shall be such as are necessary to attain water quality standards for BCCs at the point of discharge. Thus, they shall be set (1) equal to the most stringent water quality criteria or values for the BCCs in question, or (2) at a more stringent level than the most stringent water quality criteria or values if necessary due to background concentrations to meet such criteria and values at the point of discharge.

4. States may grant mixing zones beyond the dates specified in paragraphs 2 and 3 of

this section, where it can be demonstrated on a case-by-case basis that failure to grant a mixing zone would preclude water conservation measures that would lead to overall load reductions in BCCs, even though higher concentrations of BCCs occur in the effluent. Such mixing zones must also be consistent with sections C and D of this procedure.

C. *Deriving TMDLs for Discharges to Lakes.* This section addresses conditions for deriving TMDLs for Open Waters of the Great Lakes (OWGL), inland lakes and other waters of the Great Lakes System with no appreciable flow relative to their volumes.

1. Individual point source WLAs shall assume no greater dilution than one part effluent to 10 parts receiving water (containing background levels of pollutants) for implementation of numeric or narrative chronic criteria and values (including, but not limited to Tier I and Tier II HNVs, HCVs, chronic aquatic life, and wildlife criteria and values), unless, subject to restrictions for BCCs in section B of this procedure, an alternative mixing zone is demonstrated as appropriate in a mixing zone study conducted pursuant to section E of this procedure.

a. *Implementing Numeric Criteria and Values.* Unless an alternative mixing zone is approved, WLAs based upon protection of aquatic life, wildlife and human health from chronic effects shall not exceed:

$$WLA \leq 11(criterion) - 10(background)$$

Where:

Criterion = a numeric criterion or value designed to protect aquatic life, wildlife criterion or value, and/or human health from chronic adverse effects (including, but not limited to a Tier I or Tier II HNV, HCV, chronic aquatic life criterion or value, or a wildlife criterion or value derived pursuant to this Guidance) specified in units of mass per unit of volume;

Background = background concentration determined pursuant to section A.8 of this procedure, specified in units of mass per unit of volume; and

A demonstration for a smaller or larger mixing zone may be provided, approved and implemented in accordance with section E of this procedure. In no case shall the permitting authority grant a mixing zone based on a mixing zone demonstration which exceeds the area where discharge-induced mixing occurs.

2. Appropriate dilution assumptions to be used in calculating load allocations for nonpoint sources shall be determined, consistent with applicable State requirements, on a case-by-case basis by the authority establishing the TMDL.

3. In cases where background concentrations exceed numeric or narrative criteria or values, the WLA shall be set to zero or a multiple source TMDL shall be established that ensures attainment of criteria or values and control of BCCs pursuant to section B of this procedure.

4. WLAs based on acute aquatic life criteria or values shall not exceed the Final Acute Value.

5. The final TMDL shall include the most stringent of the WLAs derived pursuant to sections C.1, 3 and 4 of this procedure.

D. *Deriving TMDLs and WLAs/LAs for Discharges to Great Lakes System Tributaries.* This section applies to tributaries and connecting channels of the Great Lakes that exhibit appreciable flows relative to their volumes.

1. *Stream design flow.* The appropriate stream design flow used in TMDL development shall be:

a. Either the 7-day, 10-year low flow (7Q10) or the 4-day, 3-year biologically-based design flow for chronic aquatic life criteria or values;

b. The harmonic mean flow for human health criteria or values; and

c. The 30-day, 5-year low flow (30Q5) for wildlife criteria or values.

2. *Tributary Basin.* When a TMDL is established for a tributary basin or watershed within a tributary basin:

a. An adequate MOS shall be identified in the TMDL and shall include but may not be necessarily limited to the unused capacity provided by not utilizing more than the allowable dilution flow defined in section D.3.c.ii of this procedure;

b. When available information indicates that a mixing zone for a point source extends in an OWGL or CCGL, the WLA is determined using the more stringent dilution allowance provided in either section C.1 or D.3.c of this procedure;

c. WLAs shall not exceed the FAV to ensure protection of aquatic life from acute effects;

d. The WLA for a particular point source shall be the more stringent of either:

i. The portion of the loading capacity for the basin or portion thereof, which is not allocated to LAs, MOS, reserve capacity (if any) and WLAs for other point source dischargers; or

ii. The WLA developed using the procedures in section D.3 of this procedure.

e. Tributary basin TMDLs shall be based on the assumption that a pollutant does not degrade. If, however, each of the following conditions are met, the regulatory authority may take into account degradation of a pollutant:

i. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant will occur under the full range of environmental conditions expected to be encountered; and

ii. The field studies and other relevant information address other factors that affect the level of pollutants in the water column including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

3. *Source Specific TMDLs.* Source specific TMDLs shall be calculated in accordance with this section. The procedures in this section are applicable only when background concentrations (see section A.8 of this procedure) at the source location prior to the addition of discharge pollutants do not exceed criteria and values. In other situations, the regulatory authority shall develop a TMDL in accordance with section D.2 of this procedure.

a. An adequate MOS shall be identified in the TMDL and shall include unused capacity provided by not utilizing more than the allowable dilution flow determined in section D.3.c.ii of this procedure.

b. Where there is information that a mixing zone for a point source discharge extends from a tributary into an OWGL or a connecting channel, the WLA for that point source discharge shall be determined by applying the procedures in section C.1 of this procedure or section D.3.c of this procedure, whichever is more stringent.

c. *Existing Sources.* TMDLs based upon chronic aquatic life, wildlife and human health criteria or values shall be developed in accordance with the following requirements:

i.

$$WLA \leq \frac{(criterion)\left[Q_{ad} + (1-f)(effluent\ flow)\right] - (background)Q_{ad}}{effluent\ flow} \quad (X)$$

Where:

Criterion = a numeric criterion or value, designed to protect aquatic life, wildlife, and/or human health from chronic adverse effects (including, but not limited to, a Tier I or Tier II HNV, HCV, chronic aquatic life criterion or value, or a wildlife criterion or value derived pursuant to this procedure) specified in units of mass per unit of volume.

Q_{ad} = allowable dilution flow as calculated in section D.3.c.ii of this procedure,

f = fraction of the source flow that is withdrawn from the receiving water,
Effluent flow = flow rate of the discharger specified in units of volume per time,
Background = background concentration at the discharge location calculated pursuant to section A.8 and specified in units of mass per unit of volume,
X = a conversion factor which converts units of mass per unit volume to units of mass per unit time.

ii. The allowable dilution flow (Q_{dil}) will be determined by multiplying the stream design flow by the dilution fraction specified in either section D.3.c.iii or section E.3 of this procedure.

iii. Unless an alternative mixing zone is allowed consistent with section E, the dilution fraction is based upon the ratio of the 7Q10 to the effluent flow. If the ratio is:

(a) less than or equal to 250, the dilution fraction shall be no greater than 0.25;

(b) greater than 250 but less than 300, the dilution fraction shall be no greater than the result of the following equation:

$$\text{Dilution fraction} = \frac{103 - 0.31(7Q10 / \text{Source Flow})}{100}$$

(c) is equal to or greater than 300, the dilution fraction shall be no greater than 0.1.

d. *New Sources.* WLAs based upon chronic aquatic life, wildlife and human health criteria or values shall equal the criteria or values, unless a mixing study is provided, approved, and implemented in accordance with section E of this procedure. In no case shall a demonstration result in a mixing zone which provides greater dilution than is provided by section D.3.c.ii of this procedure.

e. *Existing and New Sources.* WLAs based on acute aquatic life criteria or values for both existing and new sources shall not exceed the Final Acute Value.

f. The final WLA for an existing point source is the most stringent value calculated under paragraphs c and e. The final WLA for a new point source is the most stringent value calculated under sections D.3.d and D.3.e of this procedure.

E. *Mixing Zone Demonstration Requirements.* 1. A mixing zone demonstration must:

a. Describe the degree of dilution occurring at the boundaries of the proposed mixing zone and the size, shape, and location of the area of mixing, including the manner in which diffusion and dispersion occur;

b. Define the location at which discharge-induced mixing ceases for sources to the open waters of the Great Lakes;

c. Document the substrate character and geomorphology within the mixing zone;

d. Show that the mixing zone does not interfere with or block passage of fish or aquatic life;

e. Show that the mixing zone does not extend to drinking water intakes;

f. Show that the mixing zone would not otherwise interfere with the designated uses of the receiving water or downstream waters; and

g. Document background water quality concentrations.

2. In addition, the mixing zone demonstration shall address the following factors:

a. Whether or not adjacent mixing zones overlap;

b. Whether organisms would be attracted to the area of mixing as a result of the effluent character;

c. Whether the habitat supports endemic or naturally occurring species;

d. That the mixing zone does not promote undesirable aquatic life or result in a dominance of nuisance species; and

e. That by allowing additional mixing/dilution:

i. Substances will not settle to form objectionable deposits;

ii. Floating debris, oil, scum, and other matter in concentrations that form nuisances will not be produced;

iii. Objectionable color, odor, taste or turbidity will not be produced.

3. For situations where a mixing zone demonstration, as set forth in sections E.1 and E.2 of this procedure, has been provided by the point source or any interested party, if the permitting authority approves the demonstration made according to the conditions outlined above, an adjustment for existing sources of non-BCCs to the dilution ratio specified in section C.1 of this procedure or the dilution fraction specified in section D.3.c.iii of this procedure may be made. The maximum adjustment to the dilution ratio specified in section C.1.a of this procedure shall reflect the dilution available in the area where discharged induced mixing occurs. The adjustment to the dilution fraction in section D.3.c.iii of this procedure shall not increase the dilution fraction to greater than 0.75.

4. The mixing zone demonstration shall be based on the assumption that a pollutant does not degrade within the proposed mixing zone, except that the regulatory authority may take into account degradation of a pollutant provided each of the following conditions are met:

a. Scientifically valid field studies or other relevant information demonstrate that degradation of the pollutant will occur under the full range of environmental conditions expected to be encountered; and

b. The field studies and other relevant information include other factors that affect the level of pollutants in the water column, including, but not limited to, resuspension of sediments, chemical speciation, and biological and chemical transformation.

Procedure 4: Additivity

[Reserved]

Procedure 5: Reasonable Potential To Exceed Water Quality Standards

If a permitting authority determines that a pollutant is or may be discharged into the Great Lakes System at a level which will cause, have the reasonable potential to cause, or contribute to an excursion above any Tier I criterion or Tier II value, the permitting authority shall incorporate a water quality-based effluent limitation (WQBEL) in an NPDES permit for the discharge of that pollutant. When facility-specific effluent monitoring data are available, the permitting authority shall make this determination by developing preliminary effluent limitations and comparing those effluent limitations to the projected effluent quality (PEQ) of the discharge in accordance with the following procedures. In addition, the permitting authority shall use any relevant information that indicates a reasonable potential to exceed any Tier I criterion or Tier II value.

A. Developing Preliminary Effluent Limitations on the Discharge of a Pollutant From a Point Source

1. In accordance with procedure 3 this appendix, the permitting authority shall develop preliminary wasteload allocations for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon any existing Tier I criteria. Where there is no Tier I criterion, the permitting authority shall calculate a Tier II value for such pollutant and the preliminary wasteload allocations shall be based upon such values. Where there is insufficient data to calculate a Tier II value, the permitting authority shall apply the procedure set forth in section D of this procedure to determine whether data must be generated to calculate a Tier II value.

2. The permitting authority shall develop preliminary effluent limitations consistent with the preliminary wasteload allocations developed pursuant to section A.1 of this procedure, and in accordance with existing State or Tribal procedures for converting wasteload allocations into water quality-based effluent limitations. At a minimum:

a. The preliminary effluent limitations based upon criteria and values for the protection of human health and wildlife shall be expressed as monthly limitations;

b. The preliminary effluent limitations based upon criteria and values for the protection of aquatic life from chronic effects shall be expressed as either monthly limitations or weekly limitations; and

c. The preliminary effluent limitations based upon the criteria and values for the protection of aquatic life from acute effects shall be expressed as daily limitations.

B. Determining Reasonable Potential for Pollutants Where There Are Ten or More Effluent Data Samples

1. If 10 or more facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to the Open Waters of the Great Lakes or to a free-flowing stream where the effluent flow rate is less than the stream seven-day, 10-year flow, the permitting authority shall apply the following procedures:

a. The permitting authority shall specify the PEQ as the greater of the maximum effluent concentration or the 99th percentile of the distribution of the daily values of the facility-specific effluent monitoring data. If the PEQ as either the maximum effluent concentration or calculated as the 99th percentile of the distribution of the data exceeds the preliminary effluent limitation based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 99th percentile of the distribution of monthly averages of the facility-specific effluent monitoring data. If the PEQ exceeds the preliminary effluent limitation based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 99th percentile of the distribution of weekly averages of the facility-specific effluent monitoring data. If the PEQ exceeds the preliminary effluent limitation based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant.

d. As an alternative to the procedures set forth in procedures 5.B.1.a through 5.B.1.c of this appendix, the permitting authority may calculate the PEQ as the 95 percent confidence level of the 95th percentile based on a log-normal distribution of the effluent concentration. In calculating the PEQ, the permitting authority shall identify the number of effluent samples and the coefficient of variation of the effluent data, obtain the appropriate multiplying factor from Table 1 of procedure 6 of appendix F, and multiply the maximum effluent concentration by that factor. The coefficient of variation of the effluent data shall be calculated as the ratio of the standard deviation of the effluent data divided by the arithmetic average of the effluent data. If the PEQ exceeds any of the preliminary effluent limitations developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant.

2. If 10 or more facility-specific effluent monitoring data samples are available for a pollutant discharged from a point source to a free flowing stream where the effluent flow rate is equal to or greater than the stream seven-day, 10-year flow, the permitting authority shall apply the following procedures:

a. The permitting authority shall specify the PEQ as the greater of the maximum effluent concentration and the 99th percentile of the distribution of the daily values of the facility-specific effluent monitoring data. If the PEQ, as either the maximum effluent concentration or calculated as the 99th percentile of the distribution of the data, exceeds 50 percent of the preliminary effluent limitation based on the criteria and values for the protection of aquatic life from acute effects developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant;

b. The permitting authority shall calculate the PEQ as the 99th percentile of the distribution of monthly averages of the facility-specific effluent monitoring data. If the PEQ exceeds 50 percent of the preliminary effluent limitation based on criteria and values for the protection of aquatic life from chronic effects, human health or wildlife developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant; and

c. The permitting authority shall calculate the PEQ as the 99th percentile of the distribution of weekly averages of the facility-specific effluent monitoring data. If the PEQ exceeds 50 percent of the preliminary limitation based on criteria and values to protect aquatic life from chronic effects developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant.

C. Determining Reasonable Potential for Pollutants Where There Are Less Than Ten Effluent Data Samples

If less than 10 representative effluent data samples are available for a pollutant discharged from a point source, the permitting authority shall apply the following procedures:

1. Calculate the PEQ as follows: a. Determine the number of data samples available for the pollutant discharged from the point source and the corresponding multiplying factor from Table F5–1 of this appendix:

b. The PEQ shall be the product of the appropriate multiplying factor and the maximum effluent concentration.

2. If the PEQ exceeds any of the preliminary effluent limitations developed in accordance with section A of this procedure, the permitting authority shall establish a WQBEL in an NPDES permit for such pollutant.

D. Developing Necessary Data To Calculate Tier II Values Where Such Data Does Not Currently Exist

1. Except as provided in sections D.2, D.3 or E of this procedure, for each pollutant listed in Table 6 of part 132 that a permittee reports as known or believed to be present in its effluent at a level for which data sufficient to calculate Tier II values for noncancer human health, wildlife, acute aquatic life and chronic aquatic life does not exist, the permitting authority shall:

a. Use all available, relevant information, including Quantitative Structure Activity Relationship information and other relevant toxicity information, to estimate ambient screening values for such pollutant which will protect humans from health effects other than cancer, aquatic life from acute and chronic effects, and wildlife.

b. In accordance with procedure 3 of this appendix, the permitting authority shall develop preliminary wasteload allocations for the discharge of the pollutant from the point source to protect human health, wildlife, acute aquatic life, and chronic aquatic life, based upon the estimated ambient screening values.

c. The permitting authority shall develop preliminary effluent limitations in accordance with section A.2 of this procedure, and consistent with the preliminary wasteload allocations developed in accordance with section D.1.b of this procedure.

d. The permitting authority shall compare the PEQ developed according to the procedures set forth in sections B and C of this procedure to the preliminary effluent limitations developed in accordance with section D.1.c of this procedure. If the PEQ exceeds any of the preliminary effluent limitations (or 50 percent of any of the preliminary effluent limitations where the pollutant is being discharged into a free-flowing stream where the discharger design flow is equal to or greater than the stream 7-day, 10-year flow), the permitting authority shall generate, or require the permittee to generate, the data necessary to derive Tier II values for noncancer human health, wildlife, acute aquatic life and chronic aquatic life.

e. The data generated in accordance with section D.1.d of this procedure shall be used in calculating Tier II values as required under section A.1 of this procedure.

2. A permitting authority is not required to apply the procedures set forth in section D.1 of this procedure, and include WQBELs to protect aquatic life on the discharge of any pollutant listed in Table 6 of part 132, other than bioaccumulative chemicals of concern, by an existing point source into the Great Lakes System, if:

a. There is insufficient data to calculate a Tier I criterion or Tier II value for aquatic life for such pollutant;

b. The permittee has demonstrated through a biological assessment that there are no acute or chronic effects on aquatic life in the receiving water; and

c. The permittee has demonstrated in accordance with procedure 6 of this appendix that the whole effluent does not exhibit acute or chronic toxicity.

3. Nothing in sections D.1 or D.2 of this procedure shall preclude or deny the right of a permitting authority to:

a. Determine, in the absence of the data necessary to derive a Tier II value, that the discharge of the pollutant will cause, have the reasonable potential to cause or contribute to an excursion above a narrative criterion for water quality; and

b. To incorporate a WQBEL for the pollutant into an NPDES permit.

4. If the permitting authority develops a water quality-based effluent limitation consistent with section D.3 of this procedure, it shall not be obligated to generate or require the permittee to generate the data necessary to derive a Tier II value or values for that pollutant.

E. Determining Reasonable Potential for Intake Water Pollutants

1. The permitting authority may determine that there is no reasonable potential for the discharge of an identified intake water pollutant or pollutant parameter to cause or contribute to an excursion above a narrative or numeric water quality criterion within a State or Tribal water quality standard if the permittee demonstrates that:

a. The facility withdraws 100 percent of the intake water containing the pollutant from the same body of water into which the discharge is made;

b. The facility does not contribute any additional mass of the identified intake water pollutant to its wastewater;

c. The facility does not alter the identified intake water pollutant chemically or physically in a manner that would cause adverse water quality impacts to occur that would not occur if the pollutants were left in-stream;

d. The facility does not increase the identified intake water pollutant concentration at the edge of the mixing zone, or at the point of discharge if a mixing zone is not allowed, as compared to the pollutant concentration in the intake water; and

e. The timing and location of the discharge would not cause adverse water quality impacts to occur from the discharge of the identified intake water pollutant that would not occur if the pollutants were left in-stream.

2. Upon demonstration of the conditions in section E.1 of this procedure, the permitting authority is not required to include a water quality-based effluent limitation for the identified intake water pollutant in the facility's permit, provided:

a. The NPDES permit fact sheet or statement of basis summarizes the basis for the determination that there is no reasonable potential for the discharge of an identified intake water pollutant to cause or contribute to an excursion above a narrative or numeric water quality criterion and references appropriate supporting documentation included in the administrative record;

b. The permit requires all influent, effluent, and ambient monitoring necessary to demonstrate that the conditions in section E.1 of this procedure are maintained during the permit term; and

c. The permit contains a reopener clause authorizing modification or revocation and reissuance of the permit if new information indicates changes in the conditions in section E.1 of this procedure.

3. Absent demonstration of the conditions in section E.1 of this procedure, the permitting authority shall use the procedures under sections A through D of this procedure to determine whether a discharge has the reasonable potential to cause or contribute to an excursion above a narrative or numeric water quality criterion.

4. This section does not alter the permitting authority's existing obligation to develop effluent limitations consistent with the assumptions and requirements of any available waste load allocation for the discharge prepared by the State or Tribe and approved by EPA pursuant to 40 CFR 130.7.

F. Other Applicable Conditions

1. In addition to the above procedures, effluent limitations shall be established to comply with all other applicable State, Tribal and Federal laws and regulations, including technology-based requirements and antidegradation policies.

2. When determining whether water quality-based effluent limitations are necessary, information from chemical-specific, whole effluent toxicity and biological assessments shall be considered independently.

3. If the geometric mean of a pollutant in fish tissue samples collected from a water body exceeds the tissue basis of a Tier I criterion or Tier II value, after consideration of the variability of the pollutant's bioconcentration and bioaccumulation in fish, each facility that discharges detectable levels of such pollutant has the reasonable potential to cause or contribute to an excursion above a Tier I criteria or a Tier II value and the permitting authority shall establish a WQBEL for such pollutant in the NPDES permit for such facility.

Tables to Procedure 5 of Appendix F

TABLE F5–1

Number of samples	Multiplying factor for CV=0.6
1	6.2
2	3.8
3	3.0
4	2.6
5	2.3
6	2.1
7	2.0
8	1.9
9	1.8

Procedure 6: Whole Effluent Toxicity Requirements for Point Sources

A. Whole Effluent Toxicity Requirements

The following requirements shall apply to all discharges:

1. No discharge shall exceed 1.0 acute toxic unit (TU_a) at the point of discharge;

2. No discharge shall cause or contribute to causing any point in a receiving water to exceed 1.0 chronic toxic unit (TU_c); provided that, at the discretion of the permitting authority, the foregoing requirement shall not apply (i) within a mixing zone, or (ii) in any portion of a receiving water for which a permitting authority has demonstrated that due to the site-specific physical and hydrological conditions, it is unnecessary to apply any chronic whole effluent toxicity (WET) requirements to protect aquatic life; and

3. No discharge shall cause or contribute to causing an excursion above any numeric WET criteria or narrative criteria for water quality within a State or Tribal water quality standard.

B. WET Test Methods

All WET tests performed pursuant to this procedure 6 shall be performed in accordance with test procedures approved under 40 CFR part 136. If there are no test procedures for WET approved under 40 CFR part 136, all WET tests performed pursuant to this procedure shall be performed in accordance with:

1. "Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms", EPA/600/4–90/027;

2. "Short-Term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms", EPA/600/4–89/001, and Supplement, EPA/600/4–89/001a (except Method #1001 and #1003); or

3. other acute or chronic toxicity testing methods determined to be acceptable by the permitting authority.

C. Permit Conditions

1. Where a permitting authority determines that a discharge violates or has the reasonable potential to violate the requirements of section A of this procedure, the permitting authority:

a. Shall establish a water quality-based effluent limitation (WQBEL) or WQBELs for WET to ensure compliance with section A of this procedure;

b. Shall calculate the WQBEL to ensure compliance with the requirements of section A.2 of this procedure based upon the dilution calculations specified in sections C and D of procedure B3 of this appendix;

c. May allow an appropriate schedule of compliance consistent with procedure 9 of this appendix; and

d. May decide that WQBELs for WET are not necessary if the State or Tribe's water quality standard does not contain a numeric criterion for WET, and the permitting authority demonstrates in the fact sheet or statement of basis of the NPDES permit that chemical-specific effluent limits are sufficient to ensure compliance with section A of this procedure.

2. Where a permitting authority does not determine that a discharge violates or has the reasonable potential to violate the requirements of section A of this procedure, but the permitting authority lacks sufficient data to demonstrate pursuant to section D that the discharge does not violate or have the reasonable potential to violate the requirements of section A of this prodedure, then the permitting authority shall include:

a. WET testing requirements in NPDES permits to generate the data needed to adequately characterize the aquatic toxicity of the effluent; and

b. Appropriate language requiring the initiation and completion of a toxicity reduction evaluation by the permittee if the toxicity testing data required by section 6.C.2.a of this appendix indicate that the discharge violates or has reasonable potential to violate the requirements of section A of this procedure.

3. Where sufficient data are available for a permitting authority to determine pursuant to section D of this procedure that a discharge does not violate or have the reasonable potential to violate the requirements in

section A of this procedure, the permitting authority shall not be required to include in the permit those conditions set forth in section C.2 of this procedure, but may do so at its discretion.

D. Reasonable Potential Determinations

The permitting authority shall take into account the factors described in 40 CFR 122.44(d)(1)(ii) in determining whether a discharge causes, has the reasonable potential to cause, or contributes to a violation of the requirements of section A of this procedure. In cases where facility-specific WET effluent data are available, a permitting authority shall use the following procedures in determining whether a discharge causes, has the reasonable potential to cause, or contributes to a violation of section A of this procedure:

1. The permitting authority shall characterize the toxicity of the discharge by:

a. Averaging acute toxicity values collected within the same day for each species;

b. Averaging chronic toxicity values collected within the same calendar month for each species; and

c. When either chronic or acute toxicity values are unavailable, estimating the missing result by using an effluent-specific acute/chronic ratio, except that when there is no effluent-specific acute/chronic ratio, the missing value shall be predicted using a default acute/chronic ratio of 10.

2. A discharge causes, has the reasonable potential to cause, or contributes to a violation of 1.0 TUa when sufficient effluent-specific information demonstrates that:

$$\frac{50\%}{\%\ \text{effect in 100\% effluent}} < B$$

where the effect is immobilization or mortality of the test organism in the WET test and B is the multiplying factor taken from Table F6–1 of this procedure. Where there are less than ten individual WET tests, the multiplying factor taken from Table F6–1 of this procedure shall be based on a coefficient of variation (CV) of 0.6. Where there are ten or more individual WET tests, the multiplying factor taken from Table F6–1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests by the arithmetic mean of the WET tests.

3. A discharge causes, has the reasonable potential to cause, or contributes to water quality outside of an allocated mixing zone exceeding 1.0 TU_c if:

$$\left[\text{chronic toxicity } (TU_c) \text{ of the effluent}\right] > 1/(B \times RWC)$$

where B is the multiplying factor taken from Table F6–1 of this procedure and RWC is the receiving water concentration of the effluent expressed in decimal form. Where there are less than ten individual WET tests, the multiplying factor taken from Table F6–1 of this procedure shall be based on a CV of 0.6. Where there are ten or more individual WET tests, the multiplying factor taken from Table F6–1 of this procedure shall be based on a CV calculated as the standard deviation of the WET tests by the arithmetic mean of the WET tests. For discharges to Tributaries of the Great Lakes System, RWC is determined by dividing the source flow by the $Q_{7\text{-}10}$, where the facility's water supply is the receiving water or by dividing the source flow by the quantity of the source flow plus the $Q_{7\text{-}10}$, where the facility's water supply is not the receiving water. For discharges to open waters of the Great Lakes, RWC is the source flow divided by 11. When B is greater than one/RWC, the permitting authority shall review the raw toxicity test data available to determine whether the discharge causes, has the reasonable potential to cause, or contributes to causing water quality outside of an allocated mixing zone to exceed 1.0 TU_c.

E. References

U.S. EPA. 1990. Methods for Measuring the Acute Toxicity of Effluents and Receiving Waters to Freshwater and Marine Organisms, EPA/600/4–90/027, NTIS #PB–91–167–650.

U.S. EPA. 1989. Short-term Methods for Estimating the Chronic Toxicity of Effluents and Receiving Waters to Freshwater Organisms, EPA/600/4–89/001 (except Method #1001 and #1003), NTIS #PB–89–207–013.

U.S. EPA. 1989. The Supplement to Short-term Methods for Estimating the Chronic Toxicity of Effluents in Receiving Waters to Freshwater Organisms, EPA/600/4–89/001a, NTIS #PB–90–145–764.

Tables to Procedure 6 of Appendix F

TABLE F6–1.—REASONABLE POTENTIAL MULTIPLYING FACTORS: 95% CONFIDENCE LEVEL AND 95% PROBABILITY BASIS

Number of samples	Coefficient of variation																			
	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
1	1.4	1.9	2.6	3.6	4.7	6.2	8.0	10.1	12.6	15.5	18.7	22.3	26.4	30.8	35.6	40.7	46.2	52.1	58.4	64.9
2	1.3	1.6	2.0	2.5	3.1	3.8	4.6	5.4	6.4	7.4	8.5	9.7	10.9	12.2	13.6	15.0	16.4	17.9	19.5	21.1
3	1.2	1.5	1.8	2.1	2.5	3.0	3.5	4.0	4.6	5.2	5.8	6.5	7.2	7.9	8.6	9.3	10.0	10.8	11.5	12.3
4	1.2	1.4	1.7	1.9	2.2	2.6	2.9	3.3	3.7	4.2	4.6	5.0	5.5	6.0	6.4	6.9	7.4	7.8	8.3	8.8
5	1.2	1.4	1.6	1.8	2.1	2.3	2.6	2.9	3.2	3.6	3.9	4.2	4.5	4.9	5.2	5.6	5.9	6.2	6.6	6.9
6	1.1	1.3	1.5	1.7	1.9	2.1	2.4	2.6	2.9	3.1	3.4	3.7	3.9	4.2	4.5	4.7	5.0	5.2	5.5	5.7
7	1.1	1.3	1.4	1.6	1.8	2.0	2.2	2.4	2.6	2.8	3.1	3.3	3.5	3.7	3.9	4.1	4.3	4.5	4.7	4.9
8	1.1	1.3	1.4	1.6	1.7	1.9	2.1	2.3	2.4	2.6	2.8	3.0	3.2	3.3	3.5	3.7	3.9	4.0	4.2	4.3
9	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.1	2.3	2.4	2.6	2.8	2.9	3.1	3.2	3.4	3.5	3.6	3.8	3.9
10	1.1	1.2	1.3	1.5	1.6	1.7	1.9	2.0	2.2	2.3	2.4	2.6	2.7	2.8	3.0	3.1	3.2	3.3	3.4	3.6
11	1.1	1.2	1.3	1.4	1.6	1.7	1.8	1.9	2.1	2.2	2.3	2.4	2.5	2.7	2.8	2.9	3.0	3.1	3.2	3.3
12	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.6	2.7	2.8	2.9	3.0	3.0
13	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.4	2.5	2.5	2.6	2.7	2.8	2.9
14	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.8	1.9	2.0	2.1	2.2	2.3	2.3	2.4	2.5	2.6	2.6	2.7
15	1.1	1.2	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.8	1.9	2.0	2.1	2.2	2.2	2.3	2.4	2.4	2.5	2.5
16	1.1	1.1	1.2	1.3	1.4	1.5	1.6	1.6	1.7	1.8	1.9	1.9	2.0	2.1	2.1	2.2	2.3	2.3	2.4	2.4
17	1.1	1.1	1.2	1.3	1.4	1.4	1.5	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.2	2.2	2.3	2.3
18	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.6	1.6	1.7	1.7	1.8	1.9	1.9	2.0	2.0	2.1	2.1	2.2	2.2

TABLE F6–1.—REASONABLE POTENTIAL MULTIPLYING FACTORS: 95% CONFIDENCE LEVEL AND 95% PROBABILITY BASIS—Continued

Number of samples	Coefficient of variation																			
	0.1	0.2	0.3	0.4	0.5	0.6	0.7	0.8	0.9	1.0	1.1	1.2	1.3	1.4	1.5	1.6	1.7	1.8	1.9	2.0
19	1.1	1.1	1.2	1.3	1.3	1.4	1.5	1.5	1.6	1.6	1.7	1.8	1.8	1.9	1.9	2.0	2.0	2.0	2.1	2.1
20	1.1	1.1	1.2	1.2	1.3	1.4	1.4	1.5	1.5	1.6	1.7	1.7	1.8	1.8	1.8	1.9	1.9	2.0	2.0	2.0

Procedure 7: Loading Limits

Whenever a water quality-based effluent limitation (WQBEL) is developed based upon the provisions of procedures 3 and 5 of this appendix, or other State procedures except for pollutants which cannot be appropriately expressed in terms of mass, the WQBEL shall be established as both a concentration value and an equivalent mass loading rate value.

A. Both values shall be consistent in terms of daily or weekly, and monthly averages, or in other appropriate time-related terms.

B. The mass loading values shall be calculated using the effluent flow rate values that are consistent with those used in the development of WQBEL concentration values pursuant to procedures 3 and 5 of this appendix, or other State procedures.

Procedure 8: Water Quality-Based Effluent Limitations Below the Levels of Quantification

When a water quality-based effluent limitation (WQBEL) for a pollutant is determined to be less than the minimum level (ML) of the most sensitive analytical technique specified in or approved under 40 CFR part 136, the permitting authority shall use the following strategy to regulate the source of that pollutant in the NPDES permit.

A. Permit Limit

Include the WQBEL in the NPDES permit, specify an analytical method and measurement frequency, and identify the compliance evaluation level (CEL) for the pollutant that is not to be exceeded. The CEL is the level at which compliance with an effluent limit is assessed. The permittee shall be given the opportunity to demonstrate that a higher level is appropriate because of matrix interference.

B. Narrative Statement

Include permit text explaining that the WQBEL for the pollutant is less than the CEL of the specified analytical method.

C. Daily, Weekly and Monthly Limits

Include text in each permit stating that any discharge of a pollutant in amounts greater than or equal to the daily CEL for that pollutant is an exceedance. Include text when a permit contains a weekly or monthly limit, (i) requiring that all discharges sampled during such time period be averaged according to procedures established by the permitting authority, and (ii) stating than an average value greater than or equal to a weekly or monthly CEL is an exceedance.

D. Program Requirement

Include a condition in the permit which requires the permittee to develop and conduct a pollutant minimization program. The goal of the pollutant minimization program shall be to reduce all potential sources of the pollutant to maintain the effluent at or below the WQBEL. The minimization program shall, as a minimum, include the following:

1. An annual review and semi-annual monitoring of potential sources of the pollutant;

2. Quarterly monitoring for the pollutant in the influent to the wastewater treatment system;

3. Submittal of a control strategy designed to proceed toward the goal of maintaining all sources of the pollutant to the wastewater collection system below the WQBEL;

4. When the sources of the pollutant are discovered, appropriate control measures shall be implemented, consistent with the control strategy; and

5. An annual status report shall be sent to the permitting authority including:

a. All minimization program monitoring results for the previous year;

b. A list of potential sources of the pollutant; and

c. All action taken to determine and eliminate the pollutant.

E. Compliance Text

Include permit text specifying that the permittee will be considered in compliance during any time period if all applicable discharge limits are being met, the Pollutant Minimization Program described in section D of this procedure is being fully performed, and all other terms and conditions of the permit are being fully satisfied.

F. BCCs

If the WQBEL is for a pollutant which is a BCC:

1. Include a condition in the permit which requires the permittee to determine if the pollutant is bioconcentrating or bioaccumulating in fish exposed to the effluent. Resident fish monitoring, caged fish monitoring, effluent pollutant bioconcentration studies, and/or application of other approvable procedures shall be required as part of the permit condition.

2. To the extent that these studies reveal unacceptable accumulation in fish tissue as a result of the discharge, the control strategy required by section D.3 of this procedure shall be reviewed and modified as appropriate. For purposes of the foregoing, "unacceptable accumulation" shall be determined by: (i) Comparing the level of the pollutant in the monitored fish tissue to the level used to develop the water quality criteria for that pollutant (accounting for the variability of the bioconcentration test and for the calculated dilution of the effluent flow in the receiving water), or (ii) calculating the effluent concentration of the pollutant from fish tissue monitoring and comparing the result to the water quality criteria for that pollutant (accounting for the variability of the bioconcentration test and for the calculated dilution of the effluent flow in the receiving water).

G. Other Conditions

The permit may also require the development and implementation of other innovative monitoring programs. These programs would be determined on a case-by-case basis and may include:

1. New analytical equipment and methods more sensitive than the analytical method specified in the permit;

2. Internal waste stream monitoring and mass balance modeling techniques; and

3. Other innovative monitoring techniques capable of adequately determining the compliance status of the effluent.

Procedure 9: Compliance Schedules

A. New or More Restrictive Limitations for New or Increasing Dischargers

When a permit is issued, reissued or modified to contain an effluent limitation derived from a Tier I criterion or Tier II value, whole effluent toxicity criterion or narrative criterion to address a new or increased discharge, the permittee shall comply with the new effluent limitation upon the commencement of the new or increased discharge.

B. New or More Restrictive Limitations for Existing Discharges

1. Any existing permit which is reissued or modified to contain a new or more restrictive effluent limitation based upon a Tier I criterion or Tier II value, whole effluent toxicity criterion, or narrative criterion may allow a reasonable period of time, not to exceed the term of the permit or three years, whichever is less, for the permittee to comply with that limit, provided that the Tier I criterion, Tier II value, whole effluent toxicity criterion, or narrative criterion was adopted (or, in the case of a narrative criterion, was newly interpreted) after July 1, 1977.

2. If a permit establishes a schedule of compliance which exceeds one year from the date of permit issuance, the schedule shall set forth interim requirements and the dates for their achievement. The time between interim dates for compliance schedules under this provision may not exceed one year. If the time necessary for completion of any interim requirement is more than one year and is not readily divisible into stages for completion, the permit shall specify interim dates which shall be at least annual for the submission of progress reports toward completion of the interim requirements and indicate a projected completion date.

C. Delayed Effectiveness of Tier II Limitations for Existing Dischargers

Whenever a limit based upon a Tier II value is included in a final permit issued to an existing discharger, the permit may provide a reasonable period of time up to two years in which to provide additional studies necessary to develop a Tier I criterion or to modify the Tier II value. In such cases, the permit shall require compliance with the Tier II limitation within a reasonable time no later than three years after permit issuance and contain a reopener clause allowing permit modification if specified studies have been provided by the permittee or any person during the time allowed for generation of additional data. If the permittee or any person demonstrates through additional studies that a revised limit is appropriate, that limit shall be incorporated through permit modification and a reasonable time period allowed for compliance up to the permit term. If the specified studies have been performed and do not demonstrate that a revised limit is appropriate, the permitting authority may provide the permittee a reasonable additional time with which to achieve compliance with the original effluent limitation within the remaining term of the permit. The limit revised based upon additional studies is not affected by the anti-backsliding provisions of section 402(o) of the Clean Water Act.

D. Definitions

Existing discharger. Any facility that commenced discharging prior to *[insert the effective date of final rule]*, provided it is not an increasing discharger.

Increasing discharger. An existing discharger that on or after *[insert the effective date of final rule]* has an increase in flow, concentration or loading from that which was previously specified in its permit.

New discharger. Any facility that commences discharging on or after *[insert the effective date of final rule]*.

[FR Doc. 93–7832 Filed 4–15–93; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 131, and 132

[FRL–4613–8]

RIN 2040–AC08

Proposed Water Quality Guidance for the Great Lakes System

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed rule; correction.

SUMMARY: EPA is making corrections to the preamble to the proposed rule for the Water Quality Guidance for the Great Lakes System which appears elsewhere in this separate part of the **Federal Register**. The corrections provide missing text and changes that were inadvertently omitted during editing of the proposed rule. In addition, EPA is encouraging commenters on the Guidance to provide one copy of their comments in electronic format.

DATES: EPA will accept public comments on the proposed Guidance including the corrections until September 13, 1993. Comments postmarked after this date may not be considered.

ADDRESSES: An original and 4 copies of all comments on the proposed Guidance including the corrections should be addressed to Wendy Schumacher, Water Quality Branch (WQS–16J), U.S. EPA, Region V, 77 West Jackson Blvd., Chicago, Illinois, 60604 (telephone: 312–886–0142). In addition, EPA encourages commenters to provide one copy of their comments in electronic format, preferably 5.25″ or 3.5″ diskettes compatible with WordPerfect for DOS.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Fenner, Water Quality Branch Chief (WQS–16J), U.S. EPA Region V, 77 W. Jackson Blvd., Chicago, Illinois, 60604 (Telephone: 312–353–2079).

SUPPLEMENTARY INFORMATION: This document provides corrections to several paragraphs in the preamble to the proposed Water Quality Guidance for the Great Lakes System ("Guidance") developed under section 118(c)(2) of the Clean Water Act (CWA), and published elsewhere in this separate part of the **Federal Register**. This Guidance, once finalized, will establish minimum water quality standards, antidegradation policies, and implementation procedures for waters within the Great Lakes System in the States of New York, Pennsylvania, Ohio, Indiana, Illinois, Minnesota, Wisconsin, and Michigan, including the waters within the jurisdiction of Indian Tribes.

The corrections provide missing text and changes that were inadvertently omitted during editing of the proposed rule.

Correction 1

Replace the 17th paragraph in section I.A.4.b of the preamble with the two new paragraphs below. The revision corrects an inadvertent omission of text that references the source of measured concentrations of pollutants in fish tissue in the Great Lakes system, references a recent EPA study, and requests additional comments. The two new paragraphs would read:

These substances appear to be approaching equilibrium in the Great Lakes System at unacceptably high levels due to continuing loadings from a variety of sources, such as: (1) Historically contaminated sediments in the embayments as well as the open lakes; (2) tributary inputs resulting from point sources, spills and direct runoff from urban and rural areas, and/or resuspension from contaminated sediments; and (3) atmospheric deposition of pollutants.

Concentrations measured in 1990 in lake trout in Lake Michigan of PCBs and chlorinated pesticides exceed the fish tissue concentrations that correspond to current EPA 304(a) water quality criteria by several orders of magnitude (Table I–1) (DeVault 1993a). As discussed above, coho salmon respond much faster to changes in water column concentrations than lake trout. If a new equilibrium is being reached given current mass loadings, then substantial further reductions in mass loadings to the lakes will be necessary to eliminate fish advisories.

EPA recently released a national study on chemical residues in fish (EPA, 1992). Many of the fish samples evaluated in the study were from sites in the Great Lakes basin known to be influenced by various point and nonpoint sources. EPA invites comments on the applicability of data from the study to the analysis of toxic pollutants in the Great Lakes ecosystem.

Correction 2

Replace the fifth paragraph of section II.E.1.b of the preamble with the new paragraph below. The editorial changes that were inadvertently omitted clarify the Agency's position that the proposed Guidance would be applicable to decisions under other statutes "to the extent independent regulatory authority requires compliance with the Clean Water Act." The new paragraph would read:

Finally, upon incorporation into enforceable State, Tribal, or Federal laws, the criteria and values or appropriate site-specific modifications developed under the proposed Guidance will apply to a wide range of regulatory decisions, including decisions under other statutes to the extent independent regulatory authority requires compliance with the Clean Water Act. Examples of such application include:

Correction 3

Replace the sixth paragraph of section II.I of the preamble with the new paragraph below. The text inadvertently omitted reference to Table 5. The new paragraph would read:

For pollutants other than those listed in Tables 1, 2, 3, 4, and 5, the requirements of § 132.5(e)(2) are intended to ensure that State or Tribal criteria methodologies and narrative implementation procedures result in criteria or values equal to or more restrictive than the proposed Guidance methodology produces.

Correction 4

Replace the fourth sentence of the first paragraph of section IV.B.5 of the preamble with the three new sentences below. The text corrects a reference to the chemicals that the Agency believes may be affected by the use of bioaccumulation factors. The three new sentences would read:

This change will result in more stringent criteria for a number of chemicals in the Great Lakes system. The chemicals most affected would be those listed as bioaccumulative chemicals of concern and potential bioaccumulative chemicals of concern in Table 6 of part 132. This change is also consistent with EPA's existing guidance ("Technical Support Document for Water Quality-based Toxics Control" (EPA 505/2–90–001) and draft "Assessment and Control of Bioconcentratable Contaminants in Surface Waters" (56 FR 13150)).

Correction 5

Replace the third last paragraph of section VII.D.3.g of the preamble with the new paragraph below. The editorial changes that were inadvertently omitted clarify the scenario presented in the preamble. The new paragraph would read:

In this scenario, the return to the higher production rate may be subject to antidegradation, depending on the timing of the previous production patterns and whether or not they are reflected in the effluent limits and EEQ baseline conditions established at the

time of permit reissuance. As discussed above, information from the preceding permit term should be used to determine the effluent quality. The permit writer has the flexibility to use the most representative information from the preceding permit term in making the determination. The permit writer could account for a recent downturn in production by setting the effluent limits and establishing EEQ baseline conditions to reflect conditions prior to the downturn. In this case, permit limits would already be set at levels that will accommodate a return to historic production levels. In contrast, if a production decrease was in evidence over the previous permit term and likely to continue, the permit would likely establish effluent limits and baseline EEQ conditions at the level representative of the previous permit term, and a firm seeking to return to production levels achieved in an earlier time period would be subject to antidegradation (if changes to these permit limits are necessary to accommodate this increase in production).

Correction 6

Replace the third sentence of the last paragraph of section VII.F.3.e of the preamble with the new sentence below. The editorial changes that were inadvertently omitted add the words "or analyze the cost-effectiveness of a pollution prevention alternative" to the sentence. The new sentence would read:

While the proposed Guidance does not explicitly require cost/benefit or cost effectiveness analyses, in determining what is prudent and feasible EPA believes that the Director will likely weigh the cost of the pollution prevention measures against the benefits with regard to the reductions in pollutant loading or analyze the cost-effectiveness of a pollution prevention alternative.

Correction 7

Replace the last digit of the Educational Resources Information Center (ERIC) order numbers for documents appearing in section XIII of the preamble with the capital letter "D" This change corrects a typographical error in editing. For example, the ERIC order number for document A in section XIII should read "390D" instead of "3900". Similar changes should be made in the ERIC order numbers for these documents wherever they may appear in the preamble, rule text, and appendixes.

Electronic Submission of Comments

EPA is encouraging people who submit comments on the proposed Guidance to provide one copy of their comments in electronic format. Having comments in electronic format will facilitate analysis of the comments received, and will help ensure comments on specific topics are efficiently addressed. EPA believes that because a large majority of commenters will probably use microcomputers to prepare the comments, it may be relatively easy for commenters to prepare a diskette copy of the comments. EPA would welcome comments in any common diskette format, but prefers 5.25" or 3.5" diskettes compatible with WordPerfect for DOS to reduce chances for incorrect transfers from different formats to the format EPA is likely to use.

Submission of a copy of the comments in electronic format is voluntary. EPA will give full consideration to comments whether or not they are accompanied by a copy in electronic format.

Submission of comments in electronic format does not eliminate the need for commenters to provide an original and four copies of comments in hardcopy format.

To facilitate public review of the Guidance, diskette copies of the Guidance and selected supporting materials are available from the addresses shown in section XIII of the preamble. The NTIS order number is PB–93–504–504. The ERIC order number is 526D.

Dated: April 8, 1993.

Tudor T. Davies,

Acting Assistant Administrator.

[FR Doc. 93–8659 Filed 4–15–93; 8:45 am]

BILLING CODE 6560–01–P

federal register

Friday
April 16, 1993

Part III

Department of Education

Applications for New Awards Under the Program for Children With Severe Disabilities; Notice

DEPARTMENT OF EDUCATION

[CFDA No. 84.086J]

Application Notice for New Awards for Statewide Systems Change Under the Program for Children With Severe Disabilities for Fiscal Year (FY) 1993

Purpose: On August 25, 1992 the Office of Special Education and Rehabilitative Services (OSERS) published a notice in the **Federal Register** inviting applications for new awards for FY 1993 at 57 FR 38488. The closing date was December 11, 1992 for the transmittal of applications and the Secretary intends to make awards under the August 25, 1992 notice.

Subsequent to the publication of the notice inviting applications, Congress allocated additional funds to be used for this competition. Therefore, OSERS is announcing a second competition and announcing a second date for transmittal of applications. This notice announces a second competition and new deadline date only for applications under the Statewide Systems Change competition (CFDA 84.086J). Any applicant wishing to apply or reapply should request a new application package.

Deadline for Transmittal of Applications: June 4, 1993.

Deadline for Intergovernmental Review: August 4, 1993.

Applications Available: April 19, 1993.

Available Funds: $1,000,000.

Estimated Range of Awards: $240,000–260,000.

Estimated Size of Awards: $250,000.

Estimated Number of Awards: 4.

Project Period: Up to 60 months.

Note: The Department is not bound by any estimates in this notice.

Applicable Regulations: (a) The Education Department General Administrative Regulations, 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85 and 86; and (b) The regulations for this program in 34 CFR part 315.

Priorities: The final priority for this program was published in the **Federal Register** on April 8, 1992 at 57 FR 12080 as Statewide Systems Change.

For Applications or Information Contact: Patricia Hawkins, U.S. Department of Education, 400 Maryland Avenue, SW., room 4617, Switzer Building, Washington, DC 20202–2734. Telephone: (202) 205–8164. Deaf and hearing impaired individuals may call (202) 205–6170 for TDD services.

Authority: 20 U.S.C. 1424.

(Catalog of Federal Domestic Assistance No. 84.086: Program for Children with Severe Disabilities.)

Dated April 8, 1993.

William L. Smith,

Acting Assistant Secretary, Office of Special Education and Rehabilitative Services.

[FR Doc. 93–8907 Filed 4–15–93; 8:45 am]

BILLING CODE 4000–01–M

federal register

Friday
April 16, 1993

Part IV

Department of Education

34 CFR Parts 777 et al.
Programs for Library Research and Demonstration, Improving Access to Research Library Resources, and College Library Technology and Cooperation Grants; Proposed Rule

DEPARTMENT OF EDUCATION

34 CFR Parts 777, 778, and 779

RIN 1850–AA47

Library Research and Demonstration Program; Improving Access to Research Library Resources Program; College Library Technology and Cooperation Grants Program

AGENCY: Department of Education.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Secretary proposes to amend the regulations governing the Library Research and Demonstration Program, the Improving Access to Research Library Resources Program (formerly the Strengthening Research Library Resources program), and the College Library Technology and Cooperation Grants Program. These proposed amendments are needed to implement the Higher Education Amendments of 1992 (1992 Amendments) (Pub. L. 102–325, enacted on July 23, 1992), to reflect changes in the Education Department General Administrative Regulations (EDGAR), and to clarify and restructure certain provisions in the existing regulations governing the programs.

DATES: Comments must be received on or before May 17, 1993.

ADDRESSES: All comments concerning these proposed regulations should be addressed to Louise V. Sutherland or Frank A. Stevens, U.S. Department of Education, 555 New Jersey Avenue NW., room 404, Washington, DC. 20208–5571.

A copy of any comments that concern information collection requirements also should be sent to the Office of Management and Budget at the address listed in the Paperwork Reduction Act section of this preamble.

FOR FURTHER INFORMATION CONTACT: Louise V. Sutherland or Frank A. Stevens. Telephone: (202) 219–1315. Individuals who are hearing impaired may call the Federal Dual Party Relay Service at 1–800–877–8339 (in the Washington, DC 202 area code, telephone 708–9300) between 8 a.m. and 7 p.m., Eastern time.

SUPPLEMENTARY INFORMATION: Under the Library Research and Demonstration Program, the Secretary provides grants for research, development, and demonstration projects related to the improvement of libraries and education in library and information science. Under the Improving Access to Research Library Resources Program, the Secretary provides financial assistance to major research libraries to help maintain and strengthen their collections and to help make their holdings available to other libraries. Under the College Library Technology and Cooperation Grants Program, the Secretary provides four types of grants to encourage the use of technology to enhance library resource sharing. These include networking grants, combination grants, services to institutions grants, and research and demonstration grants.

By promoting high quality research and education, these programs further the National Education Goals. In particular, they support Goal Five, which calls for every adult American to be literate and to possess the knowledge and skills necessary to compete in a global economy.

I. The Library Research and Demonstration Program (Part 777)

The Library Research and Demonstration Program is authorized by section 223 of title II, part B, of the Higher Education Act of 1965, as amended (HEA). The major change to section 223 in the 1992 Amendments is the addition of projects to enhance library services through effective and efficient use of new technologies to the list of projects that the Secretary is authorized to fund under this program.

In addition to this change, which is required by statute and incorporated in § 777.10 of the regulations, the major changes the Secretary proposes to make to the existing regulations governing this program are as follows:

- Throughout part 777, the term "librarianship" would be replaced with the term "library and information science" to reflect technological developments in the field and to be consistent with the statute and other library programs.
- Section 777.4 would be revised to add a definition for "library and information science." The definition proposed is broader than the existing definition of "librarianship" and is based on the definition of the term developed by the American Library Association.
- Section 777.10 would be revised to provide increased flexibility by removing existing provisions that restrict the means by which grantees may use grant funds to improve their libraries.

II. Improving Access to Research Library Resources Program (Part 778)

The Improving Access to Research Library Resources Program is authorized by title II, part C, of the HEA. The 1992 Amendments changed the title of the program from Strengthening Research Library Resources to Improving Access to Research Library Resources. The 1992 Amendments also removed the College Library Resources Program, previously authorized under section 211 of the Act, and the corresponding exclusion of grant recipients under that program from eligibility for grants under this program. In addition to changing the title and § 778.3 to reflect these statutory changes, the Secretary proposes to amend the selection criteria by increasing the points for the budget and cost-effectiveness criterion to ten and by reducing the points for the description of the project to five. These changes are proposed based on experience in selecting recipients and the comments of peer reviewers over the past several years.

III. The College Library Technology and Cooperation Grants Program (Part 779)

The College Library Technology and Cooperation Grants Program formerly authorized under title II, part D, of the HEA, is now authorized by part A. The 1992 Amendments also made the following changes to this program:

- The minimum amount of any grant under this program has been increased from $15,000 to $25,000.
- The amount of a networking grant has been capped at $50,000.
- The Secretary is required to give priority for networking grants to institutions of higher education seeking assistance for projects that will assist developing institutions.
- The types of activities that are authorized under networking grants have been expanded to include upgrading technological equipment.
- The purpose of networking grants has been expanded to include organizing, accessing, or utilizing material in electronic formats.
- The purpose of combination grants has been clarified to provide that it is for the accessing and sharing of library and information resources.

In addition to the changes required to incorporate these amendments to the statute, the major regulatory changes proposed by the Secretary are as follows:

- A new § 779.6 would be added to implement the developing institutions priority for networking grants by requiring the Secretary to announce a priority each year in the Federal Register.
- Section 779.21 would be revised to subdivide among the special selection criteria the 40 points that currently are allotted generally for special selection criteria. This section also would be revised to create a more parallel format for the special selection criteria for all four categories of grants. These changes

would enable peer reviewers to exercise more precision in assessing grant applications. The Secretary also proposes to revise the special selection criteria for all four categories of grants to increase the emphasis on applications that propose to utilize technologies in concert with evolving networks such as the National Research and Education Network (NREN), a program that was specifically mentioned by the Congress in its revision of the purpose of networking grants. The Secretary particularly requests comment on this proposed change.

• Section 779.6 would be revised to add two definitions and modify one. The term "developing institution of higher education" would be added to the definitions and would be defined by referencing the existing standards for identifying developing institutions under 34 CFR part 607 (Strengthening Institutions Program). The term "library and information science" would replace the term "librarianship" throughout 34 CFR part 779 and would be defined, consistent with professional society standards, to reflect the current state of technology in the field. In addition, the definition of "network" would be revised to reflect recent technological developments and to be consistent with the definition in the Library Services and Construction Act.

Executive Order 12291

These proposed regulations have been reviewed in accordance with Executive Order 12291. They are not classified as major because they do not meet the criteria for major regulations established in the order.

Regulatory Flexibility Act Certification

The Secretary certifies that these proposed regulations would not have a significant economic impact on a substantial number of small entities, because they largely affect major institutions of higher education and nonacademic libraries. The entities that would be affected by these proposed regulations are a limited number of small academic and nonacademic libraries. However, the regulations would not have a significant economic impact on the small academic and nonacademic libraries because the regulations would not impose excessive regulatory burdens or require unnecessary Federal supervision. The regulations would impose minimal requirements to ensure the proper expenditure of program funds.

Paperwork Reduction Act of 1980

Sections 777.31, 778.21, 778.22, and 779.21 contain information collection requirements. As required by the Paperwork Reduction Act of 1980, the Department of Education will submit a copy of these sections to the Office of Management and Budget (OMB) for its review. (44 U.S.C. 3504(h))

Public and private nonprofit institutions of higher education and nonacademic libraries are eligible to apply for grants under these regulations. Annual public reporting burden for this collection of information is estimated to average 30 hours per response for 375 respondents, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, room 3002, New Executive Office Building, Washington, DC 20503; Attention: Daniel J. Chenok.

Intergovernmental Review

These programs are subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for these programs.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding these proposed regulations.

All comments submitted in response to these proposed regulations will be available for public inspection, during and after the comment period, in room 404, 555 New Jersey Avenue NW., Washington, DC, between the hours of 8:30 a.m. and 4:00 p.m., Monday through Friday of each week except Federal holidays.

To assist the Department in complying with the specific requirements of Executive Order 12291 and the Paperwork Reduction Act of 1980 and their overall requirement of reducing regulatory burden, the Secretary invites comment on whether there may be further opportunities to reduce any regulatory burdens found in these proposed regulations.

Assessment of Educational Impact

The Secretary particularly requests comments on whether the proposed regulations in this document would require transmission of information that is being gathered by or is available from any other agency or authority of the United States.

List of Subjects

34 CFR Part 777

Education, Educational research, Government contracts, Grant programs—education, Libraries, Reporting and recordkeeping requirements.

34 CFR Part 778

Colleges and universities, Education, Grant programs—education, Libraries, Reporting and recordkeeping requirements, Research.

34 CFR Part 779

Colleges and universities, Education, Educational research, Grant programs—education, Libraries, Reporting and recordkeeping requirements.

Dated: March 22, 1993.

(Catalog of Federal Domestic Assistance Numbers: 84.039 Library Research and Demonstration Program; 84.091 Improving Access to Research Library Resources Program; and 84.197 College Library Technology and Cooperation Grants Program)

Richard W. Riley,

Secretary of Education.

The Secretary proposes to amend parts 777, 778, and 779 of title 34 of the Code of Federal Regulations as follows:

PART 777—LIBRARY RESEARCH AND DEMONSTRATION PROGRAM

1. The authority citation for part 777 continues to read as follows:

Authority: 20 U.S.C. 1021 et seq., unless otherwise noted.

2. Section 777.1 is amended by removing the period at the end of paragraph (a)(3), and adding, in its place, a semicolon, revising paragraph (b), redesignating paragraph (c) as paragraph (d), and adding a new paragraph (c) to read as follows:

§ 777.1 The Library Research and Demonstration Program.

* * * * *

(b) Education in library and information science;

(c) The effective and efficient use of new technologies to enhance library services; and

* * * * *

3. Section 777.3 is amended by revising paragraph (a) to read as follows:

§ 777.3 Regulations that apply to this program.

* * * * *

(a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) 34 CFR part 75 (Direct Grant Programs).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 82 (New Restrictions on Lobbying).

(6) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(7) 34 CFR part 86 (Drug-Free Schools and Campuses).

* * * * *

4. Section 777.4 is amended by removing the definition of "Librarianship" in paragraph (b), and adding, in its place, a new definition of "Library and information science" to read as follows:

§ 777.4 Definitions that apply to this program.

* * * * *

(b) * * *

Library and information science means the study of recordable information and knowledge and the services and technologies to facilitate their management and use. The term encompasses information and knowledge creation, communication, identification, selection, acquisition, organization, description, storage, retrieval, preservation, analysis, interpretation, evaluation, synthesis, dissemination, and management.

5. Section 777.10 is revised to read as follows:

§ 777.10 Authorized activities.

The Secretary may award a grant for a project that supports research, development, demonstration, or any combination of these, related to—

(a) The improvement of libraries;

(b) Education in library and information science;

(c) The enhancement of library services through effective and efficient use of new technologies; and

(d) The dissemination of information derived from a project funded under the program.

(Authority: 20 U.S.C. 1021, 1033)

PART 778—[AMENDED]

6. The title of part 778 is revised to read as follows:

PART 778—IMPROVING ACCESS TO RESEARCH LIBRARY RESOURCES PROGRAM

7. The authority citation for part 778 continues to read as follows:

Authority: 20 U.S.C. 1021, 1041, 1042, unless otherwise noted.

8. Section 778.1 is amended by removing "Strengthening" from the heading and the undesignated introductory text, and adding in its place "Improving Access to" both times it appears, and by correcting the spelling of "strengthen" in paragraph (a).

9. Section 778.2 is amended by correcting the spelling of "users" in paragraph (b).

10. Section 778.3 is revised to read as follows:

§ 778.3 What restrictions on eligibility apply?

The Secretary does not award a grant to an applicant otherwise eligible under this program if the applicant is eligible to receive a grant under other Federal programs, such as the Medical Library Assistance Act of 1965, for the project it proposes to receive assistance under this part, unless the applicant shows that—

(a) Payments under this part will not duplicate payments under those other Federal programs; and

(b) Special circumstances warrant assistance under this part.

(Authority: 20 U.S.C. 1021, 1041)

11. Section 778.5 is amended by revising the heading to read as follows:

§ 778.5 What are the objectives of this program?

12. Section 778.6 is amended by revising the undesignated introductory text and paragraph (a) to read as follows:

§ 778.6 What regulations apply?

The following regulations apply to this program:

(a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) 34 CFR part 75 (Direct Grant Programs).

(3) 34 CFR part 77 (Definitions that Apply to Department of Education Programs and Activities).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 82 (New Restrictions on Lobbying).

(6) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(7) 34 CFR part 86 (Drug-Free Schools and Campuses).

* * * * *

13. Section 778.22 is amended by removing "10" in paragraph (a) introductory text and adding, in its place, "5", and removing "5" in paragraph (e) introductory text and adding, in its place, "10".

PART 779—COLLEGE LIBRARY TECHNOLOGY AND COOPERATION GRANTS PROGRAM

14. The authority citation for part 779 is revised to read as follows:

Authority: 20 U.S.C. 1021 and 1029, unless otherwise noted.

15. The authority citation following §§ 779.3 through 779.5, 779.9, 779.10, 779.20 and 779.21 is revised to read as follows:

(Authority: 20 U.S.C. 1029)

16. Section 779.1 is revised to read as follows:

§ 779.1 What is the College Library Technology and Cooperation Grants Program?

(a) Under the College Library Technology and Cooperation Grants Program the Secretary provides grants of at least $25,000 for technological equipment, networking, and other special purposes designed to encourage the use of technology to enhance library resource sharing.

(b) In the case of Networking Grants, the maximum amount of a grant is $50,000.

(Authority: 20 U.S.C. 1029)

17. Section 779.2 is revised to read as follows:

§ 779.2 What types of grants does the Secretary provide?

The Secretary provides competitive grants in each of the following four categories:

(a) *Networking grants.* These grants are designed to provide assistance for the planning, development, acquisition, maintenance, or upgrading of technological equipment and software necessary to organize, access, or utilize material in electronic formats and to participate in networks for the accessing

and sharing of library and information resources.

(b) *Combination grants.* These grants are designed to provide assistance for establishing and strengthening joint-use library facilities, resources, software, or equipment for accessing and sharing library and information resources.

(c) *Services to institutions grants.* These grants are designed to provide assistance for establishing, developing, or expanding programs or projects that improve the grantee's service to institutions of higher education.

(d) *Research and demonstration grants.* These grants are designed to provide assistance for conducting research or demonstration projects to improve information services to meet special national or regional needs by utilizing technology to enhance library and information services.

(Authority: 20 U.S.C. 1029)

18. Section 779.4 is amended by revising paragraphs (b)(2) and (b)(6) to read as follows:

§ 779.4 What activities may the Secretary fund?

* * * * *

(b) * * *

(2) Acquisition, maintenance, and upgrading of equipment and supplies, including computer hardware and software;

* * * * *

(6) Dissemination of information about the project.

19. Sections 779.6, 779.7, and 779.8 are redesignated as §§ 779.7, 779.8, and 779.9, respectively.

20. A new § 779.6 is added to read as follows:

§ 779.6 What priority does the Secretary establish for networking grants?

(a) Each year, the Secretary gives priority for Networking Grants to institutions of higher education seeking assistance for projects that assist developing institutions of higher education to link with one or more institutions of higher education in resource sharing networks.

(b) The Secretary announces this priority in a notice published in the **Federal Register.**

(Authority: 20 U.S.C. 1029)

21. Redesignated § 779.7 is amended by revising paragraph (a) to read as follows:

§ 779.7 What regulations apply?

* * * * *

(a) The Education Department General Administrative Regulations (EDGAR) as follows:

(1) 34 CFR part 74 (Administration of Grants to Institutions of Higher Education, Hospitals, and Nonprofit Organizations).

(2) 34 CFR part 75 (Direct Grant Programs).

(3) 34 CFR part 77 (Definitions that Apply to Department Regulations).

(4) 34 CFR part 79 (Intergovernmental Review of Department of Education Programs and Activities).

(5) 34 CFR part 82 (New Restrictions on Lobbying).

(6) 34 CFR part 85 (Governmentwide Debarment and Suspension (Nonprocurement) and Governmentwide Requirements for Drug-Free Workplace (Grants)).

(7) 34 CFR part 86 (Drug-Free Schools and Campuses).

* * * * *

22. In redesignated § 779.8, paragraph (b) is amended by removing the definition of "Librarianship", revising the definitions of "Institution of higher education" and "Network", and adding new definitions of "Developing institution of higher education" and "Library and information science" in alphabetical order to read as follows:

§ 779.8 What definitions apply?

* * * * *

(b) * * *

Developing institution of higher education means an institution of higher education that is designated as an eligible institution under 34 CFR part 607 in the most recent announcement of eligible institutions.

Institution of higher education means a public or nonprofit private institution of higher education as defined in 34 CFR 600.4.

* * * * *

Library and information science means the study of recordable information and knowledge and the services and technologies to facilitate their management and use. The term encompasses information and knowledge creation, communication, identification, selection, acquisition, organization description, storage, retrieval, preservation, analysis, interpretation, evaluation, synthesis, dissemination, and management.

* * * * *

Network means any local, statewide, regional, interstate, or international cooperative association of library entities that provides for the systematic and effective coordination of the resources of school, public, academic, and special libraries and information centers for improved supplementary services for the clientele served by each type of library entity.

23. Section 779.21 is amended by revising paragraph (b) to read as follows:

§ 779.21 What selection criteria does the Secretary use?

* * * * *

(b) *Special program criteria.* An applicant may receive up to 40 points under the special program criteria in this section for each category of grant, as follows:

(1) *Networking grants.* The Secretary uses the following special criteria to evaluate each Networking Grant application:

(i) *Need and commitment* (15 points). The Secretary reviews each application to determine the extent to which—

(A) There is a need for special assistance as evidenced by the inability of the institution, because of fiscal constraints, institutional size, or other factors, to plan, develop, acquire, maintain, or upgrade technological equipment with its existing resources and to participate in resource-sharing networks; and

(B) There is evidence of strong institutional willingness to share library and information resources, participate in cooperative arrangements with other libraries, and take part in evolving networks such as the National Research and Education Network.

(ii) *Impact* (25 points). The Secretary reviews each application to determine the extent to which—

(A) The project will strengthen the academic programs of the institution;

(B) The applicants will possess, after an award of a grant under this program, equipment and software compatible with the evolving National Research and Education Network; and

(C) The project will increase local, regional, and national access to and the sharing of the institution's library and information resources.

(2) *Combination grants.* The Secretary uses the following special criteria to evaluate each Combination Grant application:

(i) *Need and commitment* (15 points). The Secretary reviews each application to determine the extent to which—

(A) There is a need for special assistance as evidenced by the inability of the institutions to establish and strengthen joint use of library facilities, resources, or equipment with their existing resources because of fiscal constraints, institutional size, or other factors; and

(B) There is evidence of strong institutional willingness to share their library and information resources, participate in cooperative arrangements with other libraries or networks of libraries, and take part in evolving networks such as the National Research and Education Network.

(ii) *Impact* (25 points). The Secretary reviews each application to determine the extent to which—

(A) The project will strengthen the academic programs of the participating institutions;

(B) The applicants will possess, after an award of a grant under this program, equipment and software compatible with evolving networks such as the National Research and Education Network; and

(C) The project will increase local, regional, and national access to and the sharing of their institutions' library and information resources.

(3) *Services to institutions grants.* The Secretary uses the following special criteria to evaluate each Services to Institutions Grant application:

(i) *Need and commitment* (20 points). The Secretary reviews each application to determine the extent to which—

(A) There is evidence that the project is needed and desired by institutions of higher education, including those to be served by the project; and

(B) There is evidence that formal written cooperative agreements to provide library and information services exist between the applicant and the institutions of higher education identified in the application.

(ii) *Impact* (20 points). The Secretary reviews each application to determine the extent to which—

(A) There is evidence of the applicant's capability to continue project services and of the likelihood that the applicant will build upon the project when the grant period ends; and

(B) The project will establish, develop, or expand local, regional, and national access to and the sharing of library and information resources through evolving networks such as the National Research and Education Network.

(4) *Research and demonstration grants.* The Secretary uses the following special criteria to evaluate each Research and Demonstration Grant application:

(i) *Need* (5 points). The Secretary reviews each application to determine the extent to which there is evidence from library users, library educators, or library administrators that there is a special national or regional need for the project.

(ii) *Innovative utilization of technology* (10 points). The Secretary reviews each application to determine the extent to which the applicant proposes an innovative approach in utilizing technology to enhance library or information services.

(iii) *Consultation and dissemination* (15 points). The Secretary reviews each application to determine the extent to which—

(A) The project was developed in consultation with leading experts and takes account of current research; and

(B) The applicant provides plans to disseminate the results of the project.

(iv) *Impact* (10 points). The Secretary reviews each application to determine the extent to which the project meets special national or regional needs by utilizing technology to enhance library or information services through evolving networks such as the National Research and Education Network.

[FR Doc. 93–8906 Filed 4–15–93; 8:45 am]

BILLING CODE 4000-01-U

federal register

Friday
April 16, 1993

Part V

Department of Justice

Office of Juvenile Justice and Delinquency Prevention

Missing Children's Assistance Act; Notice

DEPARTMENT OF JUSTICE

Office of Juvenile Justice and Delinquency Prevention

Missing Children's Assistance Act: Video/Telecommunications Training for Law Enforcement Personnel on Techniques for Investigating Crimes Against Children

AGENCY: Office of Juvenile Justice and Delinquency Prevention, Office of Justice Programs, Justice.

ACTION: Notice of issuance of solicitation for a discretionary grant program under the Missing Children's Assistance Act.

SUMMARY: The Office of Juvenile Justice and Delinquency Prevention (OJJDP) is publishing this Notice of Competitive Discretionary Grant Programs to be funded under section 405 of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended, 42 U.S.C. 5775 (Title IV of this Act is referred to as the Missing Children's Assistance Act). The program announcement that follows contains specific instructions on competitive program requirements, including eligibility requirements and selection criteria for this competitive program. Following the program announcement is a section that summarizes general application and administrative requirements applicable to all announced programs.

DATES: The program announcement specifies a due date for the receipt of applications. Applications received after the due date will not be considered.

ADDRESSES: Applications must be received by mail or hand delivered by 5 p.m., on the due date at the Office of Juvenile Justice and Delinquency Prevention, 633 Indiana Avenue NW., Washington, DC 20531.

FOR FURTHER INFORMATION CONTACT: Program inquiries are to be addressed to the attention of the OJJDP staff contact person identified in the program announcement. For general information, contact Darlene Brown, Missing Children's Program, (202) 514–4622. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Responsibility for establishing annual research, demonstration, and service program priorities and criteria for making grants and contracts pursuant to section 405 of the Juvenile Justice and Delinquency Prevention Act of 1974, as amended (the Act), 42 U.S.C. 5775, rests with the Administrator of the Office of Juvenile Justice and Delinquency Prevention. During FY 1992, 11 new programs and two new awards for two continuing programs were announced and applications were received. None of the applications received in response to the *"Video/Telecommunications Training for Law Enforcement Personnel on Techniques for Investigating Missing and Exploited Child Cases,"* initiative were recommended for funding. OJJDP is reissuing the solicitation for new proposals for this program. Previous applicants may also submit new proposals.

The OJJDP program planning process for Fiscal Year 1993 is closely coordinated with the Assistant Attorney General and the Bureau components of the Office of Justice Programs (OJP). The Missing Children's Discretionary Program that follows in this announcement is listed below in accordance with overall OJP program priorities.

Purpose

The purpose of this project is to minimize the negative impact of law enforcement procedures on children who are victims of abuse or sexual exploitation through the development and dissemination to law enforcement personnel of a comprehensive video training curriculum designed to improve investigative response to child victims of maltreatment.

Background

The past decade has seen a substantial increase in the number of cases involving crimes against children. Studies indicate that children are 2–3 times more likely than adults to become victims of violent crime. Recent surveys of prosecutors and law enforcement agencies reflect the growing volume of child maltreatment cases handled in their offices and a heightened awareness of the responsibility of law enforcement to protect children. With the increase in child victims has come a greater demand for specialized training and technical assistance for personnel handling child maltreatment cases. Because of the nature of the crimes and the age of the victims, investigating these cases require special skills and knowledge in order to develop the best possible case and to ensure that the child does not suffer additional trauma in the investigative process.

Abducted and runaway children pose special challenges for the investigator, yet they also share many characteristics with other child victims. The majority of cases of children abducted by non-family members involve sexual assault and frequently physical abuse and injury as well. Significant number of victims of parental abduction lived in homes characterized by domestic violence and frequently experience abuse and neglect while on the run. Runaway children often run from abusive homes only to find themselves at serious risk of sexual assault and exploitation.

Investigating crimes against children presents an especially difficult challenge for small police departments. Most law enforcement agencies employ less than ten officers. Even the smallest agencies will encounter these cases, yet these law enforcement officers have few opportunities or resources to receive specialized and intensive training in the investigation of crimes against children. Specialized child abuse or abduction units are usually found only in the largest departments. Officers in smaller departments are more likely to utilize training which presents a broad approach to child victims than a specialized training course focusing only on missing and exploited children.

Rapidly developing telecommunications technologies are becoming more accessible and economical in use. According to proponents of this type of technology, these methods can provide many advantages over more traditional training and information dissemination, including cost savings in travel and time, more timely transfer of information, and greater access to larger numbers of students or interested parties.

The distribution of video training programs supported by satellite, cable, or other technology to closed user group audiences may overcome many of the barriers to receiving specialized training faced by many law enforcement agencies. Training could occur through the existing law enforcement telecommunications systems or through structured teleconferencing.

OJJDP is coordinating the development of this project with the Office for Victims of Crime (OVC) in the Department of Justice and the National Center on Child Abuse and Neglect (NCCAN) in the Department of Health and Human Services.

Goal

The goal of this project is to provide state-of-the-art information on the investigation of missing, abused, and exploited children cases to a wide audience of small to mid-size police departments.

Objectives

The objectives of the project are:

- To support development of an integrated training course curriculum; and
- To develop and test regional and national dissemination strategies

emphasizing utilization of cable and teleconferencing networks.

Program Strategy

OJJDP will select an organization to develop and produce a video training course about the investigation of crimes against children. This series of videotape presentations will focus on the investigation of missing children (including both family and non-family abductions), sexual abuse, exploitation, and other related crimes committed against children such as investigation of physical abuse injuries and homicides. Additional related topics to be addressed in training videotapes include case management, developing offender profiles, techniques for interviewing child victims and interrogating suspects, and interacting with social service, medical, and mental health professionals. Investigative techniques and strategies must reflect an understanding of the child victim and emphasize the need to prevent re-victimizing the child through the investigative process. The curriculum should focus on basic, but state-of-the-art information and techniques, and should be consistent with other OJJDP-sponsored training programs for law enforcement. The curriculum should primarily represent situations and resources available to small and mid-size law enforcement agencies.

This project requires the selection of a project advisory committee approved by OJJDP consisting of experts and practitioners from law enforcement, child protective services, the medical field, mental health services, and prosecutors. This advisory committee will assist in the development of the curriculum. The grantee should consult with law enforcement officers currently serving as faculty for OJJDP's child abuse and exploitation training program as well as the training staff from the National Center for Missing and Exploited Children.

In addition to the series of training videotapes, the successful applicant will produce a small publication or pocket card for law enforcement agencies listing national and regional resources which provide training, information, and technical assistance in cases of missing and exploited children.

The successful grantee will also design and test a plan for regional and national dissemination utilizing cable and teleconferencing networks, law enforcement training academies, and professional organizations.

Specific products to be completed during this project are:

- A training curricula including specific learning objectives;
- A series of training videos (investigation of non-family abductions, family abductions, runaways, sexual abuse, physical abuse, child homicides, sexual exploitation, interviewing child victims, interrogating suspects, effective case management, interacting with social service, medical, and mental health professionals);
- A small pamphlet or pocket card for law enforcement listing resources for training, information, and technical assistance;
- A pilot demonstration effort using telecommunications technology, and
- A summary report detailing opportunities for future dissemination.

Eligibility Requirements

Applications are invited from public agencies and private organizations which can demonstrate the capability to develop and produce a high quality series of training videos on the investigation of child maltreatment cases for law enforcement as well as the demonstrated capability for utilizing telecommunications technology for dissemination of training materials. The applicant must have an adequate command of literature and data relating to the issues addressed in this solicitation as well as significant experience in the investigation of crimes against children. The applicant must also demonstrate an understanding of the training needs and resources of small to mid-size law enforcement agencies.

Selection Criteria

Applications will be rated on the extent to which they meet the following criteria:

(1) Conceptualization of the Problem. (20 points)

The applicant must demonstrate a clear understanding of investigative issues, problems, and practices regarding child maltreatment cases and the possible application of training and telecommunications technology to law enforcement training.

(2) Statement of Objectives. (15 points)

The objectives to be achieved by the project must be clearly defined and consistent with the issues and requirements set forth in the conceptualization of the problem.

(3) Project Design. (20 points)

The project design is sound and contains program elements directly linked to the achievement of the project objectives.

(4) Project Management. (15 points)

The project's management structure and staffing must be adequate for the successful implementation and completion of the project. The management plan must describe a system whereby logistical activities are handled in the most efficient and economical way.

(5) Organizational Capability. (20 points)

The applicant organization's ability to conduct the project successfully must be documented in the proposal. Organizational experience with law enforcement investigative practices, training, development of videos, and utilization of telecommunications is crucial. Key project staff should have significant experience in the investigative practices of crimes against children.

(6) Budget. (10 points)

The proposed budget must be reasonable, allowable, and cost-effective vis-a-vis the activities to be undertaken.

Award Period

The project will be funded for 24 months.

Award Amount

Up to $200,000 has been allocated for the first 12 month budget period. Applicants must include an estimated budget for a second 12 month budget period.

Due Date

Applications must be received by mail or delivered to OJJDP by June 15, 1993.

Contact

For further information contact Frank Porpotage, Training and Technical Assistance Division, OJJDP, at (202) 307–5940.

General Application and Administrative Requirements

General application and administrative requirements and conditions, including various certifications, are implicit in this announcement. These requirements and conditions are set forth below.

Eligible Applicants

Applications are invited from eligible agencies, institutions, or individuals, public or private. Private-for-profit organizations are not eligible for special emphasis grants but are for other grants; however, they must waive their fee in order to be eligible.

Applicants must demonstrate that they have the management and financial capability to effectively implement a project of the size and scope delineated in the program description.

Each applicant must also demonstrate the capability to manage the program in

order to be eligible for funding consideration.

Application Requirements

All applicants must submit a completed Standard Form 424, Application for Federal Assistance; Standard Form 424A, Budget Information; OJP Form 4000/3, Program Narrative and Assurances; and OJP Form 4061/6 Certifications. All applications must include the information required by this solicitation as well as Standard Form 424.

The SF–424 must appear as a cover sheet for the entire application. The project summary should follow the SF–424. All other forms must then follow. Applicants should be sure to sign OJP Forms 4000/3 and 4061/6. Applicants are requested to submit the original signed application (SF–424) and four copies to OJJDP. Potential applicants should review the OJJDP Peer Review Guideline and the OJJDP Competition and Peer Review Procedures. Application forms and supplementary information will be provided upon request.

Applicants that include proposed noncompetitive contracts for the provision of specific goods and services must include a sole source justification for any procurement in excess of $25,000.

Applicants who are receiving other funds in support of the proposed activity should list the names of the other organizations that will provide financial assistance to the program and indicate the amount of funds to be contributed during the program period. Provide the title of the project, name of the public and private grantor, and amount to be contributed during this program period. Give a brief description of program.

OJJDP will notify applicants in writing of the receipt of their application. Subsequently, applicants will be notified by letter as to the decision made regarding whether or not their submission will be recommended for funding.

To comply with Executive Order 12372, applicants from State and local units of government or other organizations providing services within a State must submit a copy of their application to the State Single Point of Contact, if one exists, and if the program has been selected for review by the State.

Application Review Process

All applications will be reviewed by a panel of experts who will make recommendations to the Administrator per Section 262 of the JJDP Act and 28 CFR Part 34. The panel will assign numerical values by rating competing applicants based on the point distribution identified in the Selection Criteria section of this program solicitation. Peer reviewers' recommendations are advisory only and the final award decision will be made by the Administrator. OJJDP will negotiate specific terms of the awards with the selected applicants.

Evaluation

OJJDP required that funded programs contain plans for continuous self-assessment to keep program management informed to progress and results. Many funded projects will be considered for participation in independent evaluations initiated by OJJDP. Project management will be expected to cooperate fully with designated evaluators.

Financial Requirements

Discretionary grants are governed by the provisions of the Office of Management and Budget (OMB) Circulars applicable to financial assistance. The circulars, along with additional information and guidance, are contained in the *Financial and Administrative Guide for Grants,* Office of Justice Programs, Guideline Manual, M7100.1D available from the Office of Justice Programs. This guideline manual includes information on allowable costs, methods of payment, audit requirements, accounting systems, and financial records. This manual will be provided to all successful applicants.

Civil Rights Requirements

Sec. 809(c)(1) of the Omnibus Crime Control and Safe Streets Act (OCCSSA) of 1968, as amended, applicable to OJJDP-funded programs and projects under Section 292(b) of the JJDP Act, provides that no person in any State shall on the grounds of race, color, religion, national origin, or sex be excluded from participation in, be denied the benefits of, be subjected to discrimination under, or denied employment in connection with any program or activity funded in whole or in part with funds made available under this title. Recipients of funds under the Act are also subject to the provisions of Title VI of the Civil Rights Act of 1964; Sec. 504 of the Rehabilitation Act of 1974, as amended; Title IX of the Education Amendments of 1972; the Age Discrimination Act of 1974; and the Department of Justice Non-Discrimination Regulations 28 CFR part 42, Subparts C, D, E, and G. Upon request, applicant shall maintain such records and submit to OJJDP or OJP timely, complete and accurate information regarding their compliance with the foregoing statutory and regulatory requirements.

In the event a Federal or State court or a Federal or State administrative agency makes a finding of discrimination after a due process hearing, on the grounds of race, color, religion, national origin, or sex against a recipient of funds, the recipient will forward a copy of the finding to the Office of Civil Rights (OCR) of the Office of Justice Programs.

Certifications Regarding Lobbying; Debarment, Suspension, and Other Responsibility Matters; and Drug-Free Workplace Requirements

Applicants should refer to the regulations cited in OJP Form 4061/6 to determine the certification to which they are required to attest. A copy of the OJP Form 4061/6 will be provided upon request. Applicants should also review the instructions for certification included in the regulations before completing this form. Signature of this form provides for compliance with certification requirements under 28 CFR Part 69, "New Restrictions on Lobbying" and 28 CFR Part 67, "Government-wide Debarment and Suspension (Nonprocurement) and Government-wide Requirements for Drug-Free Workplace (Grants)." The certifications shall be treated as a material representation of fact upon which reliance will be placed when the Department of Justice determines to award the covered transaction, grant, or cooperative agreement.

Audit Requirements

In October 1984, Congress passed the Single Audit Act of 1984. On April 12, 1985, the Office of Management and Budget issued Circular A–128, "Audits of State and Local Governments," which established regulations to implement the Act. OMB Circular A–128, "Audits of State and Local Governments," outlines the requirements for organizational audits which apply to OJJDP grantees.

Institutions of higher education, hospitals, and other nonprofit organizations have the responsibility to provide for an audit of their activities not less than every two years. The required audits are to be on an organization-wide basis rather than on a grant-by-grant basis.

Disclosure of Federal Participation

Section 8136 of the Department of Defense Appropriations Act (Stevens Amendment), enacted in October 1988, requires that, "when issuing statements,

press releases for proposals, bid solicitations, and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds, including but not limited to State and local governments, shall clearly state (1) the percentage of the total cost of the program or project which will be financed with Federal money, and (2) the dollar amount of Federal funds for the project or program."

Suspension or Termination of Funding

OJJDP may suspend, in whole or in part, or terminate funding for a grantee for failure to conform to the requirements or statutory objectives of the JJDP Act. Prior to suspension of a grant, OJJDP will provide reasonable notice to the grantee of its intent to suspend the grant and will attempt informally to resolve the problem resulting in the intended suspension. Hearing and appeal procedures for termination actions are set forth in the Department of Justice regulation at 28 CFR Part 18.

John J. Wilson,

Acting Administrator, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 93–8935 Filed 4–15–93; 8:45 am]

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federal register

Friday
April 16, 1993

Part VI

Department of Housing and Urban Development

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

Funding Availability for Housing Counseling for FY 1993; Notice

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Housing-Federal Housing Commissioner

[Docket No. N-93-3554; FR 3355-N-01]

Funding Availability for Housing Counseling for FY 1993

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of Funding Availability (NOFA) For Housing Counseling.

SUMMARY: This Notice announces the availability of funding for Fiscal Year 1993 for HUD-approved housing counseling agencies to assist these agencies in providing housing counseling to homebuyers, homeowners, and renters, as set forth in HUD Handbook No. 7610.1 REV-2, dated September 1990 (the Handbook).

An applicant must, as of the date of issuance of the Request for Grant Application (RFGA), which is based on this NOFA, be a HUD-approved housing counseling agency, and must be able and willing to provide, at a minimum: (1) Delinquency and default counseling to renters and homeowners; and (2) related counseling under HUD's single family mortgage assignment program. Exceptions to these two requirements are applicants approved by HUD to provide ONLY tenant counseling or Home Equity Conversion Mortgage counseling, or prepurchase counseling, including the counseling of tenants to purchase their rental unit. An applicant agency may offer any other aspect(s) of counseling set forth in the Handbook, including Home Equity Conversion Mortgage counseling. Housing counseling services not covered by the Handbook do not qualify for eligibility for funding under this NOFA.

In the body of this document is information concerning: the purpose of this NOFA; eligibility for funding; available funding; selection criteria; and the application process, including how to apply for funding, and how selections will be made.

DATES: The application deadline (date and time) will be specified in the application kit (Request for Grant Application—RFGA). In no event, however, will applications be due before June 1, 1993. Further, applicants will have at least 30 days to prepare and submit their applications. The 30-day (or more) response period will begin to run from the first date upon which the RFGA is made available. The RFGA will specify the time by which the applications must be submitted to the appropriate HUD Regional Office. Please see Section II of this NOFA for further information on what constitutes proper and timely submission of an application.

The application deadline, as specified in the RFGA, will be firm. In the interest of fairness to all competing applicants, HUD will treat as ineligible for consideration any application that is not received on or before the due date and time specified in the RFGA. Applicants should take this practice into account and make early submission of their materials to avoid any risk of loss of eligibility brought about by unanticipated delays or other delivery-related problems.

FOR FURTHER INFORMATION CONTACT: Thomas Miles, Program Advisor, Single Family Servicing Division, Department of Housing and Urban Development, room 9178, 451 Seventh Street SW, Washington, DC 20410, telephone (202) 708-1672, or (202) 708-4594 (TDD number). (These are not toll-free numbers.)

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act Statement

The information collection requirements contained in this NOFA have been approved by the Office of Management and Budget (OMB) under section 3504(h) of the Paperwork Reduction Act of 1980 (44 U.S.C. 3504(h)), and assigned OMB control number 2535-0084.

I. Purpose and Substantive Description

A. Authority and Background

1. **Authority:** Sec. 106, Housing and Urban Development Act of 1968 (12 U.S.C. 1701x); secs. 235, 237 and 255 of the National Housing Act (12 U.S.C. 1715z, 1715z-1, 1715z-2); the HUD Appropriations Act for FY 1993 (Pub.L. 102-389, approved October 6, 1992); and HUD Handbook 7610.1, REV-2, dated September 1990.

2. Background

Section 106 of the Housing and Urban Development Act of 1968 (section 106) authorizes HUD to provide a program of housing counseling services to designated homeowners and tenants. The program authorized by section 106 (Housing Counseling Program) is divided into two distinct components: the housing counseling services and requirements provided under section 106(a), and those services and requirements provided under section 106(c).

Section 106(a) authorizes HUD to provide counseling and advice to tenants and homeowners with respect to property maintenance, financial management and such other matters as may be appropriate to assist tenants and homeowners in improving their housing conditions and in meeting the responsibilities of tenancy and homeownership. With respect to homeowners, section 106(a) states that the above-described services shall be provided to homeowners with HUD-insured mortgages; first-time homebuyers with guaranteed loans under section 502(h) of the Housing Act of 1949 (42 U.S.C. 1472(h)) (home loans guaranteed by the Farmers Home Administration); and homeowners with loans guaranteed or insured under chapter 37 of title 38, United States Code (38 U.S.C. 1801-1827) (home loans insured or guaranteed by the Department of Veterans Affairs).

Section 106(c) authorizes homeownership counseling only (no tenant counseling) and defines a homeowner eligible for counseling under this section as a homeowner whose home loan is secured by property that is the principal residence of the homeowner, who is unable to correct a home loan delinquency within a reasonable time due to a reduction in the income of the homeowner because of an involuntary loss of, or reduction in, the employment of the homeowner. Section 106(c) defines "home loan" as a loan secured by a mortgage or lien on residential property, excluding, however, a home loan that is assisted under title V of the Housing Act of 1949 (42 U.S.C. 1471-1490q).

Section 162 of the Housing and Community Development Act of 1992 (Pub.L. 102-550, approved October 28, 1992) (1992 Act) amended section 106(c) to include as eligible for homeownership counseling under section 106(c) an applicant for a mortgage if the applicant is a first-time homebuyer who meets the requirements of section 303(b)(1) of the National Affordable Housing Act (Pub.L. 101-625, approved November 28, 1992) (NAHA), and the mortgage involves a principal obligation (including such initial service charges, appraisal, inspection, and other fees as the Secretary shall approve) in excess of 97 percent of the appraised value of the property and is to be insured pursuant to section 203 of the National Housing Act. (Section 303(b)(1) of NAHA (42 U.S.C. 12852) addresses assistance for first-time homebuyers. Section 203 of the National Housing Act pertains to the insurance of mortgages by HUD.)

Under the Housing Counseling Program, HUD awards grants to public or private organizations to provide the housing counseling services authorized by section 106(a) and section 106(c).

When the Congress makes funds available to assist the Housing Counseling Program, HUD announces the availability of such funds, and invites applications from eligible agencies, through a notice published in the **Federal Register**. An agency that is approved by HUD as a housing counseling agency does not automatically receive funding. The agency must apply for such funding under a Request for Grant Application (RFGA) issued by HUD through its Regional Offices. The purpose of the housing counseling program is to promote and protect the interests of HUD, HUD-approved and other mortgagees, and housing consumers participating in HUD approved and other housing programs.

B. Allocation Amounts

1. Total Available Funding

A total amount of $6,025,000 was appropriated for housing counseling by the HUD Appropriations Act for FY 1993 (Pub.L. 102–389, approved October 6, 1992).

Of the $6,025,000, HUD will use: $500,000 to assist public housing and section 8 assisted tenants to move out of poverty-stricken areas in accordance with section 162(a) of the 1992 Act; $125,000 to help resolve a litigation matter in Boston, Massachusetts that involves housing counseling; $200,000 to continue, for FY 1993, the HUD toll-free telephone number (1–800–733–3238), established in December 1991, by which a caller may obtain the names of HUD-approved housing counseling agencies in the caller's area; and $200,000 to provide training on HUD's Home Equity Conversion Mortgage (HECM) Program to HUD-approved housing counseling agencies.

HUD also will make up to $365,000 available for the continuation of the prepurchase and foreclosure-prevention counseling demonstration authorized by section 106(d), and implemented in FY 1992. To the extent that any of the $365,000 remains available after funding the demonstration for FY 1993, HUD will make the remaining amount available under this NOFA for the counseling services specified in section 106.

Accordingly, at least $4,635,000 is available for the counseling services specified in section 106. This amount will be allocated for counseling activities as follows:

Activities	Millions
a. Housing counseling services under section 106(a) of the Housing and Urban Development Act of 1968	$2,132,100
b. Homeownership counseling under section 106(c) of the Housing and Urban Development Act of 1968	2,502,900
Total Allocation for Counseling Services	4,635,000

2. Allocation of Funds to Regional Offices

HUD Headquarters will allocate the $4,635,000 available for housing counseling services to its ten Regional Offices. The basis for the allocation is the percentage of HUD-insured single family mortgage defaults within each Region, compared to the nationwide total. Under this plan, the Regions are required, in so far as possible, to award grants in relation to the number of defaults within HUD Field Office jurisdictions. The amounts allocated to the Regions for Fiscal Year 1993 (based on the $4,635,000) are as follows:

Region	Defaults	Percentage*	Allocation
I	2,231	1.35	$62,438
II	12,515	7.56	350,250
III	17,638	10.65	493,625
IV	42,446	25.62	1,187,912
V	28,558	17.24	799,236
VI	24,139	14.58	675,564
VII	4,653	2.81	130,221
VIII	6,768	4.09	189,412
IX	23,648	14.28	661,823
X	3,020	1.82	84,519
Totals	165,616	100.00	4,635,000

*Percentages have been rounded.

3. Grant Awards by HUD Regional Offices

Regional Offices will make an equitable awarding of allocated housing counseling funds to eligible HUD-approved housing counseling agencies based upon documented need in relation to:

a. The amount of funds available; and

b. The number of successful applicants. (A determination of a "successful" applicant is based on the applicant's ability to meet the selection criteria, as specified in Section I.D. of this NOFA.)

4. Announcement of Awards

In accordance with the requirements of section 103 of the Department of Housing and Urban Development Reform Act of 1989 (HUD Reform Act) and HUD's implementing regulations at 24 CFR part 4, no selection information will be made available to applicants or other persons not authorized to receive this information during the period of HUD review and evaluation of the applications. However, applicants that are declared ineligible or late will be notified. In accordance with section 102(a)(4)(c) of the HUD Reform Act, HUD will notify the public, by notice published in the **Federal Register**, of award decisions made by HUD under this funding.

5. Grantee Reimbursement by HUD

HUD will reimburse grantees on the basis of not more that $35.00 per "counseling unit" which is defined as a *documented* face-to-face, written, or telephonic contact between:

a. The grantee's housing counselor and a client; or

b. The grantee's housing counselor and a mortgagee, landlord, service agency, creditor, credit reporting agency, governmental agency, realtor or employer, acting on behalf of a client, which results in an action or decision that:

(1) Identifies, clarifies, or assists in meeting or meets the client's housing need; or

(2) Assists in resolving or resolves the client's housing problem.

(See HUD Handbook 7610.1 REV–2, dated September 1990, paragraph 1–7 on page 1–6 for a definition of "client," "housing need," and "housing problem.")

C. Eligibility

Eligible applicants include public and private nonprofit entities with a current approval by HUD as housing counseling agencies, under the provisions of HUD Handbook No. 7610.1 REV–2, dated September 1990, or its earlier versions. Current approval refers to agencies that are on record at the applicable HUD Field Office as having been approved as a HUD counseling agency as of the date of issuance of the RFGA based on this NOFA. Agencies for which HUD has withdrawn this approval, or which have indicated, in writing, their withdrawal from HUD's housing counseling program are NOT eligible. Agencies with "conditional" re-approvals also are NOT eligible unless they satisfy HUD's requirements for removal of the "conditional" approval by the due date of applications for funding under this notice.

D. Selection Criteria

1. General Criteria

HUD, through its Regional Offices, will award housing counseling grants in Fiscal Year 1993 to selected eligible agencies. Within each Region, an eligible agency is a HUD-approved housing counseling agency that is:

a. Located within the Region's geographical jurisdiction; and

b. Provides, or proposes to provide, housing counseling within that Region. (Application eligibility and grant authority do NOT cross regional boundaries.)

2. Specific Criteria

Applications for funding under this notice will be reviewed, and grants will be awarded on the basis of an evaluation of *all* of the following criteria:

a. Amount requested by the grantee;

b. If the applicant had a HUD housing counseling grant in 1988, 1989, 1990, 1991, or 1992, the applicant's use of those funds;

c. Applicant's documented client workload ("Workload" refers to the number of clients, as defined in HUD Handbook No. 7610.1 REV–2, dated September 1990, reported by the applicant on Form HUD–9902, Housing Counseling Agency Activity Report, for 1992);

d. Client workload total for all applicants within a HUD Regional Office;

e. Amount of housing counseling funds allocated to the HUD Regional Office by headquarters;

f. Reimbursement of grantees by HUD on the basis of $35.00 per housing counseling unit;

g. Regional Offices' documented need for housing counseling services within the areas served by the applicants;

h. HUD's assessment of the applicant's previous performance as a HUD-approved housing counseling agency (i.e. Biennial Performance Review), including the submission of the required reports.

i. In the case of previous grantees, the applicant's performance under such grants in accordance with the terms of the grant agreement, including the submission of the specific reports required under the grant agreement.

II. Application Process

A. Obtaining and Submitting Applications

Applicants for grants may obtain copies of the Request for Grant Application (RFGA) from the Regional Contracting Division in the HUD Regional Office that serves the area in which the applicant agency is located. The RFGA contains the application submission address. A list of the Regional Offices and their addresses follows the text of this NOFA.

B. Application Deadline

The application deadline (date and time) will be specified in the RFGA. A timely submission means: (1) In the case of hand-delivered applications, *receipt* of the application by the designated office on or before the specified date and time; or (2) in the case of mailed applications, an application that is postmarked on or before a specific date and time.

III. Checklist of Application Submission Requirements

An applicant must submit three different types of written submissions: forms, certifications, and assurances. An applicant must submit three sets of each written submission, as specified below, with supporting documentation only as specified in the RFGA. Applicants must limit the submission of material to that required by the individual form, certification or assurance. HUD will not consider extraneous material and will discard it.

A. Forms

Each applicant will be required to submit the following completed and signed forms:

1. Standard Form 424, Application for Federal Assistance.

2. Standard Form 424B, Assurances—Non-construction Programs.

3. Form HUD–2880, Applicant/Recipient Disclosure/Update Report, as required under subpart C of 24 CFR part 12, Accountability in the Provision of HUD Assistance.

B. Certifications

Each applicant will be required to submit, at a minimum, the following certifications:

1. Certification of a Drug-Free Workplace, in accordance with the Drug-Free Workplace Act of 1988 and HUD's regulations at 24 CFR part 24, subpart F.

2. Anti-Lobbying certification in accordance with section 319 of the Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352), and the regulations at 24 CFR part 87.

C. Assurances

Each applicant will be required to submit, at a minimum, assurances regarding the applicant's housing counseling program to the effect that:

1. The applicant agency received its approval by HUD prior to the date of issuance of the applicable RFGA, and currently has approval from HUD. If a Biennial Performance Review has not been made by the HUD Field Office, then a prior approval constitutes a current approval.

2. The applicant agency provided housing counseling to clients during 1992 as indicated on the applicant's Form HUD–9902, Housing Counseling Agency Activity Report, for 1992. The applicant must submit with their response to the RFGA a copy of their 1992 Form HUD–9902. (See HUD Handbook No. 7610.1 REV–2 (September 1990) for a definition of "client.")

3. HUD has or has not conducted a performance review of the applicant agency's housing counseling program; whether, as a result of the review, HUD re-approved the agency unconditionally or conditionally; whether, if HUD granted a conditional approval because of certain agency performance deficiencies, the applicant agency corrected the deficiencies to HUD's satisfaction.

4. If the applicant agency received a counseling grant from HUD during HUD's fiscal year 1988, 1989, 1990, 1991, or 1992, the agency complied with all grant requirements.

5. The applicant agency submitted all reports required during the most recent report year under the Handbook, and the grant document, if any.

6. The number of clients listed as the applicant's documented housing counseling client workload for 1992 is correct.

7. Upon receipt of the notice of the award of a counseling grant to the applicant agency, the agency can and will immediately commence counseling services in accordance with HUD Handbook 7610.1 REV–2, dated September 1990, which requires, among other things, that the agency be familiar with the requirements of the Fair Housing Amendments Act of 1988, and other fair housing information, as set forth in HUD Handbook 7610.1 REV–2.

8. The applicant will provide, at a minimum, the following types of counseling (EXCEPTIONS are agencies approved by HUD to perform only Home Equity Conversion Mortgage (HECM) counseling or tenant counseling):

a. Delinquency and default counseling to homebuyers and homeowners, and delinquency counseling to renters; and

b. Mortgage assignment counseling to mortgagors with HUD-insured mortgages having potential for assignment to HUD under the assignment program.

9. The agency had an independent financial audit during the past twenty-four (24) months.

10. The applicant administers its housing counseling program in accordance with the Fair Housing Act, as implemented by 24 CFR part 100; title VI of the Civil Rights Act of 1964, as implemented by 24 CFR part 1; Executive Order 11063, as implemented by 24 CFR part 107; section 504 of the Rehabilitation Act of 1973; as implemented by 24 CFR part 8; and the Age Discrimination Act of 1975, as implemented by 24 CFR part 146.

11. The applicant provides its services without any conflict of interest on the part of the applicant, including its staff, that might compromise the agency's ability to represent fully the best interests of the client in accordance with HUD Handbook No. 7610.1 REV–2, dated September 1990.

12. The applicant's clients reside in the U.S. Postal Service ZIP Code areas listed by the applicant.

IV. Corrections to Deficient Applications

After the deadline for submission of applications, applications will be screened to determine whether all items were submitted. Applicants will be given an opportunity to cure nonsubstantive deficiencies in their applications. The applicant must submit corrections within 14 calendar days from the date of HUD's deficiency notification or the application will not be considered.

A. Curable Deficiencies

The kinds of deficiencies which can be cured after the submission date for applications has passed are limited to the following:

1. Lack of required signature(s) on the following documents or certifications:

a. Standard Form 424B, Assurances—Non-Construction Programs.

b. Certification of Drug-Free Workplace.

c. Anti-Lobbying Certification.

2. Failure to submit any of the above documents or certifications.

B. Noncurable Deficiencies

Failure to submit:

1. A completed and signed Standard Form 424, Application for Federal assistance.

2. A signed Housing Counseling Program assurance and all of its required documentation.

Note: HUD will *not* notify applicants who fail to submit any of the above two required documents. *Failure to submit the documents will render an application unacceptable.*

V. Other Matters

Environmental Impact

A finding of No Significant Impact with respect to the environment has been made in accordance with the Department's regulations at 24 CFR part 50 which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332). The Finding of No Significant Impact is available for public inspection between 7:30 a.m. and 5:30 p.m. weekdays at the Office of the Rules Docket Clerk, Room 10276, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410.

Federalism, Executive Order

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies and procedures contained in this NOFA will not have substantial direct effects on States or their political subdivisions, or on the distribution of power and responsibilities among the various levels of government. Specifically, the purpose of the funding under this notice is to provide grants to public and private agencies that assist and advise housing consumers about how to develop competence and responsibility in meeting their housing needs.

Family, Executive Order

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has determined that this notice of funding availability may have potential for significant beneficial impact on family formation, maintenance, and general well-being to the extent that the activities of grantees will (1) provide families with the counseling and advice they need to avoid rent delinquencies or mortgage defaults, and (2) assist families in meeting the responsibilities of homeownership and tenancy. Since the impact on the family is considered beneficial, no further review under the Order is necessary.

Accountability in the Provision of HUD Assistance

(1) Documentation and Public Access

HUD will ensure that documentation and other information regarding each application submitted pursuant to this NOFA are sufficient to indicate the basis upon which assistance was provided or denied. This material, including any letters of support, will be made available for public inspection for a five-year period beginning not less than 30 days after the award of the assistance. Material will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. In addition, HUD will include the recipients of assistance pursuant to this NOFA in a **Federal Register** notice of all recipients of HUD assistance awarded on a competitive basis. (See 24 CFR 12.14(a) and 12.16(b), and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these requirements.)

(2) Disclosures

HUD will make available to the public for five years all applicant disclosure reports (HUD Form 2880) submitted in connection with this NOFA. Update reports (also Form 2880) will be made available along with the applicant disclosure reports, but in no case for a period generally less than three years. All reports—both applicant disclosures and updates—will be made available in accordance with the Freedom of Information Act (5 U.S.C. 552) and HUD's implementing regulations at 24 CFR part 15. (*See* 24 CFR subpart C, and the notice published in the **Federal Register** on January 16, 1992 (57 FR 1942), for further information on these disclosure requirements.)

Prohibitions against lobbying activities. The use of funds awarded under this NOFA is subject to the disclosure requirements and prohibitions of section 319 of the

Department of Interior and Related Agencies Appropriations Act for Fiscal Year 1990 (31 U.S.C. 1352) and the implementing regulations at 24 CFR part 87. These authorities prohibit recipients of Federal contracts, grants, or loans from using appropriated funds for lobbying the Executive or Legislative Branches of the Federal Government in connection with a specific contract, grant, or loan. The prohibition also covers the awarding of contracts, grants, cooperative agreements, or loans unless the recipient has made an acceptable certification regarding lobbying. Under 24 CFR part 87, applicants, recipients, and subrecipients of assistance exceeding $100,000 must certify that no Federal funds have been or will be spent on lobbying activities in connection with the assistance.

Indian Housing Authorities (IHAs) established by an Indian tribe as a result of the exercise of the tribe's sovereign power are excluded from coverage of the Byrd Amendment, but IHAs established under State law are not excluded from the statute's coverage.

Prohibition against lobbying of HUD personnel. Section 13 of the Department of Housing and Urban Development Act (42 U.S.C. 3537b) contains two provisions dealing with efforts to influence HUD's decisions with respect to financial assistance. The first imposes disclosure requirements on those who are typically involved in these efforts—those who pay others to influence the award of assistance or the taking of a management action by the Department *and* those who are paid to provide the influence. The second restricts the payment of fees to those who are paid to influence the award of HUD assistance, if the fees are tied to the number of housing units received or are based on the amount of assistance received, or if they are contingent upon the receipt of assistance. HUD's regulation implementing section 13 is codified at 24 CFR part 86. If readers are involved in any efforts to influence the Department in these ways, they are urged to read the final rule, particularly the examples contained in Appendix A of the rule. Appendix A of this rule contains examples of activities covered by this rule.

Any questions concerning the rule should be directed to the Office of Ethics, Room 2158, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington DC 20410. Telephone: (202) 708–3815 (voice/TDD). This is not a toll-free number. Forms necessary for compliance with the rule may be obtained from the local HUD office.

Prohibition against advance information on funding decisions. Section 103 of the HUD Reform Act proscribes the communication of certain information by HUD employees to persons not authorized to receive that information during the selection process for the award of assistance. HUD's regulation implementing section 103 is codified at 24 CFR part 4, and was recently amended by an interim rule published in the **Federal Register** on August 4, 1992 (57 FR 34246). In accordance with the requirements of section 103, HUD employees involved in the review of applications and in the making of funding decisions are restrained by 24 CFR part 4 from providing advance information to any person (other than an authorized employee of HUD) concerning funding decisions, or from otherwise giving any applicant an unfair competitive advantage. Persons who apply for assistance in this competition should confine their inquiries to the subject areas permitted by 24 CFR part 4. Applicants who have questions should contact the HUD Office of Ethics (202) 708–3815 (voice/TDD). (This is not a toll-free number.)

Catalog of Federal Domestic Assistance Program. The Catalog of Federal Domestic Assistance Program number is 14.169.

Authority: Sec. 106, Housing and Urban Development Act of 1968 (12 U.S.C. 1701x); secs. 235, 237 and 255 of the National Housing Act (12 U.S.C. 1715z, 1715z–1, 1715z–2); the HUD Appropriations Act for FY 1993 (Pub. L. 102–389, approved October 6, 1992); and HUD Handbook 7610.1, REV–2, dated September 1990.

Dated: April 12, 1993.

James E. Schoenberger,

Associate General Deputy Assistant Secretary for Housing, HD.

HUD Regional Offices

Address all inquiries to U.S. Department of Housing and Urban Development, Attention: Regional Contracting Division Director, in the Regional Office that serves your State. Telephone numbers are NOT toll-free.

Region I—Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Thomas P. O'Neill, Jr. Federal Building, 10 Causeway Street, Room 375, Boston, MA 02222–1092, (617) 565–6788

Region II—New Jersey, New York
26 Federal Plaza, New York, NY 10278–0068, (201) 264–8847

Region III—Delaware, Maryland, Pennsylvania, Virginia, Washington (D.C.), West Virginia
Liberty Square Building, 105 South 7th Street, Philadelphia, PA 19106–3392, (215) 597–8165

Region IV—Alabama, Florida, Georgia, Kentucky, Mississippi, North Carolina, Puerto Rico, South Carolina, Tennessee
Richard B. Russell Federal Building, 75 Spring Street S.W., Atlanta, GA 30303–3388, (404) 730–2705

Region V—Illinois, Indiana, Michigan, Minnesota, Ohio, Wisconsin
Ralph H. Metcalfe Federal Building, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353–6093

Region VI—Arkansas, Louisiana, New Mexico, Oklahoma, Texas
1600 Throckmorton, Post Office Box 2905, Fort Worth, TX 76113–2905, (817) 885–2851

Region VII—Iowa, Kansas, Missouri, Nebraska
Gateway Tower II, 400 State Avenue, Kansas City, KS 66101–2406, (913) 236–2102

Region VIII—Colorado, Montana, North Dakota, South Dakota, Utah, Wyoming
Executive Tower Building, 1405 Curtis Street, Denver, CO 80202–2349, (303) 844–3363

Region IX—Arizona, California, Hawaii, Nevada
Phillip Burton Federal Building and U.S. Court House, 450 Golden Gate Avenue, Post Office Box 36003, San Francisco, CA 94102–3448, (415) 556–0667

Region X—Alaska, Idaho, Oregon, Washington
Seattle Federal Office Building, 909 First Avenue, Suite 200, Seattle, WA 98104–1000, (202) 220–5122

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federal register

Friday
April 16, 1993

Part VII

Environmental Protection Agency

Premanufacture Notices; Monthly Status Report for February 1993

ENVIRONMENTAL PROTECTION AGENCY

[OPPTS–53164; FRL–4579–3]

Premanufacture Notices; Monthly Status Report for February 1993

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5(d)(3) of the Toxic Substance Control Act (TSCA) requires EPA to issue a list in the **Federal Register** each month reporting the premanufacture notices (PMNs) and exemption request pending before the Agency and the PMNs and exemption requests for which the review period has expired since publication of the last monthly summary. This is the report for February 1993.

Nonconfidential portions of the PMNs and exemption request may be seen in the TSCA Nonconfidential Information Center (NCIC), also known as the TSCA Public Docket Office, ETG–102 at the address below between 8 a.m. and noon and 1 p.m. and 4 p.m., Monday through Friday, excluding legal holidays.

ADDRESSES: Written comments, identified with the document control number "[OPPTS–53164]" and the specific PMN and exemption request number should be sent to: Document Processing Center (TS–790), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 401 M St., SW., rm. 201ET, Washington, DC 20460 (202) 260–1532.

FOR FURTHER INFORMATION CONTACT: Susan B. Hazen, Director, Environmental Assistance Division (TS–799), Office of Pollution Prevention and Toxics, Environmental Protection Agency, rm. E–545, 401 M St., SW., Washington, DC 20460 (202) 260–3725.

SUPPLEMENTARY INFORMATION: The monthly status report published in the **Federal Register** as required under section 5(d)(3) of TSCA (90 Stat. 2012 (15 U.S.C. 2504)), will identify: (a) PMNs received during February; (b) PMNs received previously and still under review at the end of February; (c) PMNs for which the notice review period has ended during February; (d) chemical substances for which EPA has received notice of commencement to manufacture during February; and (e) PMNs for which the review period has been suspended. Therefore, the February 1993 PMN Status Report is being published.

Dated: April 6, 1993.

Frank V. Caesar,

Acting Director, Information Management Division, Office of Pollution Prevention and Toxics.

Premanufacture Notice Monthly Status Report for February 1993

I. **126 Premanufacture notices and exemption requests received during the month:**

PMN No.

P 93–0496 P 93–0497 P 93–0499 P 93–0500 P 93–0501 P 93–0502 P 93–0503 P 93–0504 P 93–0505 P 93–0506 P 93–0507 P 93–0508 P 93–0509 P 93–0510 P 93–0511 P 93–0512 P 93–0513 P 93–0514 P 93–0515 P 93–0516 P 93–0517 P 93–0518 P 93–0519 P 93–0520 P 93–0521 P 93–0522 P 93–0523 P 93–0524 P 93–0525 P 93–0526 P 93–0527 P 93–0528 P 93–0529 P 93–0530 P 93–0531 P 93–0532 P 93–0533 P 93–0534 P 93–0535 P 93–0536 P 93–0537 P 93–0538 P 93–0539 P 93–0540 P 93–0541 P 93–0542 P 93–0543 P 93–0544 P 93–0545 P 93–0546 P 93–0547 P 93–0548 P 93–0549 P 93–0550 P 93–0551 P 93–0552 P 93–0553 P 93–0554 P 93–0555 P 93–0556 P 93–0557 P 93–0558 P 93–0559 P 93–0560 P 93–0561 P 93–0562 P 93–0563 P 93–0564 P 93–0565 P 93–0566 P 93–0567 P 93–0569 P 93–0570 P 93–0571 P 93–0572 P 93–0573 P 93–0574 P 93–0575 P 93–0576 P 93–0577 P 93–0578 P 93–0579 P 93–0580 P 93–0581 P 93–0582 P 93–0583 P 93–0584 P 93–0585 P 93–0586 P 93–0587 P 93–0588 P 93–0589 P 93–0590 P 93–0591 P 93–0592 P 93–0593 P 93–0594 P 93–0595 P 93–0596 P 93–0597 P 93–0598 P 93–0599 P 93–0600 P 93–0601 P 93–0602 P 93–0603 P 93–0604 P 93–0605 P 93–0607 P 93–0608 P 93–0609 P 93–0610 P 93–0611 Y 93–0050 Y 93–0051 Y 93–0052 Y 93–0053 Y 93–0054 Y 93–0055 Y 93–0056 Y 93–0057 Y 93–0059 Y 93–0060 Y 93–0061 Y 93–0062 Y 93–0063

II. **293 Premanufacture notices received previously and still under review at the end of the month:**

PMN No.

P 84–0660 P 84–0704 P 84–1145 P 85–0619 P 85–1331 P 86–0066 P 86–1315 P 86–1662 P 87–0323 P 88–0998 P 88–0999 P 88–1616 P 88–1937 P 88–1938 P 88–1980 P 88–1982 P 88–1984 P 88–1985 P 88–1999 P 88–2000 P 88–2001 P 88–2212 P 88–2213 P 88–2228 P 88–2229 P 88–2230 P 88–2236 P 88–2484 P 88–2518 P 88–2529 P 88–2540 P 89–0632 P 89–0721 P 89–0769 P 89–0775 P 89–0867 P 89–0957 P 89–0958 P 89–0959 P 89–1038 P 89–1058 P 90–0009 P 90–0158 P 90–0211 P 90–0261 P 90–0262 P 90–0263 P 90–0372 P 90–0550 P 90–0558 P 90–0559 P 90–0564 P 90–0581 P 90–0608 P 90–1280 P 90–1318 P 90–1319 P 90–1320 P 90–1321 P 90–1322 P 90–1422 P 90–1454 P 90–1527 P 90–1564 P 90–1592 P 90–1687 P 90–1745 P 90–1893 P 91–0043 P 91–0107 P 91–0108 P 91–0109 P 91–0110 P 91–0111 P 91–0112 P 91–0113 P 91–0228 P 91–0242 P 91–0243 P 91–0244 P 91–0245 P 91–0246 P 91–0247 P 91–0248 P 91–0503 P 91–0514 P 91–0548 P 91–0572 P 91–0619 P 91–0659 P 91–0689 P 91–0701 P 91–0818 P 91–0826 P 91–0914 P 91–0915 P 91–0939 P 91–0940 P 91–0941 P 91–1009 P 91–1010 P 91–1014 P 91–1015 P 91–1116 P 91–1117 P 91–1118 P 91–1131 P 91–1190 P 91–1191 P 91–1206 P 91–1210 P 91–1297 P 91–1298 P 91–1299 P 91–1324 P 91–1367 P 91–1368 P 91–1369 P 91–1386 P 91–1394 P 91–1409 P 92–0003 P 92–0031 P 92–0032 P 92–0033 P 92–0048 P 92–0129 P 92–0217 P 92–0244 P 92–0245 P 92–0246 P 92–0247 P 92–0248 P 92–0249 P 92–0250 P 92–0251 P 92–0314 P 92–0396 P 92–0412 P 92–0471 P 92–0477 P 92–0478 P 92–0545 P 92–0546 P 92–0547 P 92–0548 P 92–0549 P 92–0550 P 92–0551 P 92–0552 P 92–0595 P 92–0606 P 92–0624 P 92–0625 P 92–0649 P 92–0660 P 92–0688 P 92–0714 P 92–0776 P 92–0777 P 92–0787 P 92–0804 P 92–0813 P 92–0919 P 92–0998 P 92–0999 P 92–1003 P 92–1029 P 92–1079 P 92–1086 P 92–1116 P 92–1117 P 92–1118 P 92–1119 P 92–1125 P 92–1222 P 92–1255 P 92–1294 P 92–1295 P 92–1296 P 92–1298 P 92–1307 P 92–1308 P 92–1313 P 92–1316 P 92–1324 P 92–1337 P 92–1345 P 92–1352 P 92–1357 P 92–1364 P 92–1369 P 92–1394 P 92–1454 P 92–1455 P 92–1485 P 92–1489 P 92–1503 P 92–1504 P 92–1505 P 92–1506 P 93–0014 P 93–0015 P 93–0017 P 93–0036 P 93–0037 P 93–0038 P 93–0040 P 93–0050 P 93–0066 P 93–0067 P 93–0068 P 93–0094 P 93–0096 P 93–0097 P 93–0122 P 93–0123 P 93–0124 P 93–0126 P 93–0168 P 93–0173 P 93–0174 P 93–0175 P 93–0177 P 93–0184 P 93–0185 P 93–0186 P 93–0187 P 93–0188 P 93–0189 P 93–0190 P 93–0193 P 93–0204 P 93–0212 P 93–0213 P 93–0214 P 93–0215 P 93–0226 P 93–0227 P 93–0228 P 93–0246 P 93–0250 P 93–0251 P 93–0252 P 93–0253 P 93–0254 P 93–0255 P 93–0256 P 93–0257 P 93–0276 P 93–0277 P 93–0282 P 93–0305 P 93–0307 P 93–0313 P 93–0314 P 93–0315 P 93–0316 P 93–0317 P 93–0318 P 93–0333 P 93–0339 P 93–0343 P 93–0349 P 93–0352 P 93–0353 P 93–0357 P 93–0358 P 93–0360 P 93–0361 P 93–0362 P 93–0364 P 93–0374 P 93–0375 P 93–0376 P 93–0384 P 93–0406 P 93–0418 P 93–0419 P 93–0427 P 93–0428 P 93–0429 P 93–0430 P 93–0438 P 93–0456 P 93–0476 P 93–0477 P 93–0480 P 93–0483 P 93–0485 P 93–0491 P 93–0498 Y 93–0047

III. **113 Premanufacture notices and exemption request for which the notice review period has ended during the month. (Expiration of the notice review period does not signify that the chemical has been added to the Inventory).**

PMN No.

P 88–2518 P 90–0441 P 91–1116 P 91–1117 P 91–1118 P 91–1163 P 92–0003 P 92–0044 P 92–0599 P 92–0624 P 92–0625 P 92–0652 P 92–1009 P 92–1447 P 92–1449 P 93–0050 P 93–0066 P 93–0067 P 93–0068 P 93–0083 P 93–0098 P 93–0107 P 93–0108 P 93–0109 P 93–0110 P 93–0111 P 93–0112 P 93–0113 P 93–0114 P 93–0115 P 93–0116 P 93–0117 P 93–0118 P 93–0119 P 93–0120 P 93–0121 P 93–0125 P 93–0127 P 93–0128 P 93–0129 P 93–0130 P 93–0131 P 93–0132 P 93–0133 P 93–0134 P 93–0135 P 93–0136 P 93–0137 P 93–0138 P 93–0139 P 93–0140 P 93–0141 P 93–0142 P 93–0143 P 93–0144 P 93–0145 P 93–0146 P 93–0147 P 93–0148 P 93–0149 P 93–0150 P 93–0151 P 93–0152 P 93–0153 P 93–0154 P 93–0156 P 93–0157 P 93–0158 P 93–0159 P 93–0160 P 93–0162 P 93–0163 P 93–0164 P 93–0165 P 93–0166 P 93–0167 P 93–0169 P 93–0170 P 93–0171 P 93–0172 P 93–0176 P 93–0178 P 93–0179 P 93–0180 P 93–0181 P 93–0182. P 93–0183 P 93–0191 P 93–0192 P 93–0194 P 93–0195 P 93–0196 P 93–0197 P 93–0198 P 93–0199 P 93–0200 P 93–0201 P 93–0202 P 93–0203 P 93–0205 P 93–0206 P 93–0207 P 93–0208 P 93–0209 P 93–0210 P 93–0211 Y 93–0048 Y 93–0049 Y 93–0050 Y 93–0051 Y 93–0052 Y 93–0053 Y 93–0054

IV. 62 CHEMICAL SUBSTANCES FOR WHICH EPA HAS RECEIVED NOTICES OF COMMENCEMENT TO MANUFACTURE

PMN No.	Identity/Generic Name	Date of Commencement
P 85–1421	1,4-benzenedipentanoic acid, 2,5-dihydroxy-d,d,d',d'-tetramethyl-, dihexyl ester	January 11, 1993.
P 86–1489	G 19 c9 (och2 ch2)yoch2och2ch-oh	August 23, 1988.
P 87–1798	G Alkylester functionalized colloidal silica	December 28, 1992.
P 88–0998	G Fluorene-containing diaromatic amine	March 3, 1992.
P 88–1460	G 2,5-Dimercapto-1,3,4-thiadiazole reaction product	January 4, 1990.
P 88–1839	Benzenepropanoic acid 3-(2*h*-benzotriazol-2-yl)-5-(1,1-diethylethyl)-4-hydroxy-, methyl ester	January 6, 1993.
P 88–2169	G Cationic terpolymer of acrylamide	July 10, 1990.
P 88–2540	G Nitrate esters	February 21, 1990.
P 89–1093	G Halogenated alkane	November 20, 1990.
P 90–0093	G Reaction product of aryl and alkyl dicarboxylic acids/alkanediol/ester polyester with an acrylate adduct	January 11, 1993.
P 90–0373	G Cobalt Complex dye of monoazo dyestuff	January 6, 1993.
P 90–0375	G Copolyamide of terephthalic acid (a), isophathalic acid (b), hexamethylene diamine (c), isophoronediamine (d) and caprolactum (e)	January 3, 1993.
P 90–0558	G (4–(1-Methylbutoxy)phenyl)hydrazine monohydrochloride	October 17, 1991.
P 90–0559	1–(1-Methylbutoxy)-4-benzenamine hydrochloride	November 6, 1991
P 90–1316	G Phenoxy modified epoxy resin	December 21, 1992.
P 90–1358	Cyclohexanecarbonitrile, 1,3,3-trimethyl-5-oxo-	November 15, 1991.
P 90–1424	G Polycarbonate	January 14, 1993.
P 90–1735	G Salt of an oxygenated carboxylic acid	January 6, 1993.
P 90–1736	G Oxygenated alkyl carboxylate	January 6, 1993.
P 91–0294	G Benzeneamine,*N,N,N*,-ethyl-*N*-(substituted aryl)-4-(phenyazo)	January 6, 1992.
P 91–1104	G Substituted azo naphthalenedisulfonic acid	December 15, 1992.
P 91–1105	G Substituted azo naphthalenedisulfonic acid	December 14, 1992.
P 91–1238	Bicyclo(3.3.1)HEPT-3-*EN*-2-ol, 4,6,6-trimethyl	January 21, 1993.
P 91–1416	G Tall oil functions, vegetable oil, dibasic acids modified amide reaction product with a polyhydric alcohol	December 23, 1992.
P 92–0061	G Diamine salt of an organic acid	January 12, 1993.
P 92–0278	Benzoic acid, 4-amino-,ethyl ester, polymer with oxirane	December 18, 1992.
P 92–0406	G Hydroxy functional	January 13, 1992.
P 92–0414	G Poly-styrene-acrylic resin	January 23, 1993.
P 92–0525	G Zinc salt of an organo compound containing nitrogen	December 11, 1992.
P 92–0571	G Azo naphthalene carboxylic acid salt	December 22, 1992.
P 92–0597	G Styrene-oxagoline copolymer	December 24, 1992.
P 92–0692	G Oxo-substituted amino alkanoic acid derivative	December 26, 1992.
P 92–1012	G Substituted alkoxybenzene	December 20, 1992.
P 92–1071	G Unsaturated polyester	December 23, 1992.
P 92–1103	G Water soluble phenolic modified alkyd	December 15, 1992.
P 92–1126	G Acrylic copolymer	December 15, 1992.
P 92–1141	G Mixed polyacrylate, sodium salt	December 17, 1992.
P 92–1198	G Polyurethane prepolymer	January 4, 1993.
P 92–1199	G Monoazo dye	January 11, 1992
P 92–1259	G Polyurethane resin	December 15, 1992.
P 92–1263	1,3-Benzenedicarboxylic acid, compound with 1,6-hexanediamine	December 28, 1992.

IV. 62 Chemical Substances For Which EPA Has Received Notices of Commencement To Manufacture—Continued

PMN No.	Identity/Generic Name	Date of Commencement
P 92–1264	G Random nylon terpolymer	December 30, 1992.
P 92–1299	G Combined salt of modified rosin ester	January 8, 1993.
P 92–1309	G Cycloaliphatic acid ester	January 22, 1993.
P 92–1310	G Cycloaliphatic acid ester	January 22, 1993.
P 92–1321	G Cycloaliphatic methyl ketone	January 22, 1993.
P 92–1358	G Perfluorinated cyclo oxyaliphatic polymer	December 25, 1992.
P 92–1359	G Spiropolycyclic ketone	January 22, 1992.
P 92–1364	G Tetramethyl ammonium salts of alkylbenzene sulfonic acid	December 12, 1992.
P 92–1365	G Diazonaphoquinone sulfonic ester	December 21, 1992.
P 92–1379	G Polymethacrylate derivative with trimethyl,2-hydroxypropylammonium chloride group	December 27, 1992.
P 92–1402	Alpha-(1-oxo-C_8–C_{10}-alkyl)-omega-(C_{12},C_{16}-alkyloxy)poly(oxo-,2ethanddiyl)	January 8, 1992.
P 92–1441	G Modified polymer of ethyl acrylate and methyl methacrylate	January 6, 1993.
P 92–1473	G Mixture of reavction products of diphenylmethane diisocyanate polymer; oxirane, methyl-,poylmer withoxirane; hexanedioic acid, polymer with 1,2-propanediol; and alkanol amine with methacrylic and groups	January 13, 1993.
P 92–1480	G Perfluoroalkylethylacrylate copolymer	January 12, 1993.
P 92–1490	G Penyl and vinyl substituted silicones and silicones	January 23, 1993.
P 93–0039	G Modified starch	January 11, 1993.
P 93–0042	Fatty acids, canola-oil	January 12, 1993.
Y 88–0309	G Acrylic-styrene copolymer	December 24, 1992.
Y 93–0001	G Polyesterdiol, polymer with diisyanate and diaminoalkane	December 16, 1992.
Y 93–0002	2-Propenoic acid, polymer with methyloxirane polymer, with oxirane; monobutylether; 20% acrylic acid with 80% polyalkoxylated	December 8, 1992.
Y 93–0016	G Epoxy ester	January 12, 1993.

V. 18 Premanufacture notices for which the period has been suspended.

PMN No.

P 92–0031 P 92–0032 P 92–0033 P 93–0122 P 93–0123 P 93–0124 P 93–0126 P 93–0168 P 93–0177 P 93–0184 P 93–0185 P 93–0186 P 93–0187 P 93–0188 P 93–0189 P 93–0190 P 93–0193 P 93–0204

[FR Doc. 93–8959 Filed 4–15–93; 8:45 am]

BILLING CODE 6560–50–F

federal register

Friday
April 16, 1993

Part VIII

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonization; Draft Guideline on Detection of Toxicity to Reproduction for Medicinal Products; Availability; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93D-0140]

International Conference on Harmonization; Draft Guideline on Detection of Toxicity to Reproduction for Medicinal Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline on detection of toxicity to reproduction for medicinal products. This draft guideline was prepared by the Safety Expert Working Group of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to reflect sound scientific principles for reproductive toxicity testing.

DATES: Written comments by May 17, 1993.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Alan Taylor, Center for Drug Evaluation and Research (HFD-150), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3750.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Community (EC), Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industry Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the U.S. Food and Drug Administration, and the U.S. Pharmaceutical Manufacturers Association. In addition, the ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the organizing bodies and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

At a meeting held on September 15 and 16, 1992, the ICH Steering Committee agreed that the draft tripartite guideline entitled "Guideline on Detection of Toxicity to Reproduction for Medicinal Products" should be made available for comment. The draft guideline will be made available for comment by the European Community and Japan, as well as by FDA, in accordance with their consultation procedures. FDA is publishing the guideline to facilitate the ICH process; after the comments are analyzed and the guideline revised as necessary, FDA will determine whether it will adopt the tripartite guideline. The draft guideline addresses harmonization of testing strategies for potential reproductive toxicity and discusses issues such as selecting test species and strains, and determining test dosages and study designs.

Interested persons may, on or before May 17, 1993, submit written comments on the draft guideline to the Dockets Management Branch (address above). Two copies are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will not extend the comment period on this notice because the agency must respond to the ICH in early June.

The text of the draft guideline follows:

Guideline on Detection of Toxicity to Reproduction for Medicinal Products (Note 1)

1. Introduction

1.1 Purpose of the Guideline

There is a considerable overlap in the methodology that could be used to test chemicals and medicinal products for potential reproductive toxicity. As a first step to using this wider methodology for efficient testing, this guideline attempts to consolidate a strategy based on study designs currently in use for testing of medicinal products. It is perceived that tests in which animals are treated during defined stages of reproduction better reflect human exposure to medicinal products and allow more specific identification of stages at risk. While this approach may be useful for most medicines, long term exposure to low doses does occur and may be represented better by a one or two generation study approach.

The actual testing strategy should be determined by:

- anticipated drug use especially in relation to reproduction,
- the form of the substance and route(s) of administration intended for humans and
- making use of any existing data on toxicity, pharmacodynamics, pharmacokinetics (Note 2), similarity to other compounds in structure/activity.

To employ this concept successfully, flexibility is needed (Note 3). No guideline can provide sufficient information to cover all possible cases, all persons involved should be willing to discuss and consider variations in test strategy according to the state of the art and ethical standards in human and animal experimentation.

1.2 Aim of Studies

The aim of reproduction toxicity studies is to reveal *any* effect of one or more active substance(s) on mammalian reproduction. For this purpose both the investigations and the interpretation of the results should be related to all other pharmacological and toxicological data available to determine whether potential reproductive risks to humans are greater, lesser or equal to those posed by other toxicological manifestations. Further, repeated dose toxicity studies can provide important information regarding potential effects on adult reproduction, particularly male fertility. To extrapolate the results to humans (assess the relevance) data on likely human exposures, comparative kinetics, and mechanisms of reproductive toxicity may be helpful.

The combination of studies selected should allow exposure of mature adults *and* all stages of development from conception to sexual maturity. To allow detection of immediate and latent effects of exposure, observations should be continued through one complete life cycle, i.e. from conception in one generation through conception in the following generation. For convenience of testing this integrated sequence can be subdivided into the following stages.

A. Premating to conception (adult male and female functions, development and maturation of gametes, mating behavior, fertilisation).
B. Conception to implantation (adult female functions, early embryonic development, implantation).
C. Implantation to closure of the hard palate (adult female functions, parturition, fetal development and growth, organ development and growth).
D. Closure of the hard palate to the end of pregnancy (adult female functions, parturition, fetal development and growth, organ development and growth).
E. Birth to weaning (adult female functions, neonate adaptation to extrauterine life, postnatal development and growth).
F. Weaning to sexual maturity (postnatal development and growth, adaptation to independent life, attainment of full sexual function).

1.3 Choice of Studies

The guideline addresses the design of studies primarily for *detection* of effects on reproduction. When an effect is detected, further studies to fully characterise the nature of the response have to be designed on a case by case basis (Note 4). The rationale for the set of studies chosen should be given and should include an explanation for the choice of dosages.

Studies should be planned according to the "state of the art", and take into account preexisting knowledge of class-related effects on reproduction. They should avoid suffering and should use the minimum number of animals necessary to achieve the overall objectives. If a preliminary study is performed the results should be considered and discussed in the overall evaluation (see Note 5).

2. Animal Criteria

The animals used must be well defined with respect to their health, fertility, fecundity, prevalence of abnormalities, embryofetal deaths and the consistency they display from study to study. Within and between studies animals should be of comparable age, weight and parity; the easiest way to achieve these criteria is to use animals that are young, mature adults at the time of mating with the females being virgin.

2.1. Selection and number of species

Studies should be conducted in mammalian species. It is generally desirable to use the same species and strain as in other toxicological studies. Reasons for using rats as the predominant rodent species are practicality, comparability with other results obtained in this species and the large amount of background knowledge accumulated.

In embryotoxicity studies only a second mammalian species traditionally has been required, the rabbit being the preferred choice as a "non-rodent". Reasons for using rabbits in embryotoxicity studies include the extensive background knowledge that has accumulated, as well as availability and practicality. Where the rabbit is unsuitable, an alternative non-rodent or a second rodent species may be acceptable and should be considered on a case by case basis (Note 6).

2.2 Other test systems

Other test systems are considered to be any developing mammalian and non-mammalian cell systems, tissues, organs, or organism cultures developing independently in vitro or in vivo. Integrated with whole animal studies either for priority selection within homologous series or as secondary investigations to elucidate mechanisms of action, these systems can provide invaluable information and, indirectly, reduce the numbers of animals used in experimentation. However, they lack the complexity of the developmental processes and the dynamic interchange between the maternal and the developing organisms. These systems cannot provide assurance of the *absence* of effect nor provide perspective in respect of risk/exposure. In short, there are no alternative test systems to whole animals currently available for reproduction toxicity testing with the aims set out in the introduction (Note 7).

3. General Recommendations Concerning Treatment

3.1 Dosages

Selection of dosages is one of the most critical issues in design of the reproductive toxicity study. The choice of the high dose should be based on data from all available studies (pharmacology, acute and chronic toxicity and kinetic studies, Note 8). A repeated dose toxicity study of about 2–4 weeks duration provides a close approximation to the duration of treatment in segmental designs of reproductive studies. When sufficient information is not available preliminary studies are advisable (see Note 5).

Having determined the high dosage, lower dosages should be selected in a descending sequence, the intervals depending on kinetic and other toxicity factors. Whilst it is desirable to be able to determine a "no observed adverse effect level", priority should be given to setting dosage intervals close enough to reveal any dosage related trends that may be present (Note 9).

3.2 Route and frequency of administration

In general the route or routes of administration should be similar to those intended for human usage. One route of substance administration may be acceptable if it can be shown that a similar distribution (kinetic profile) results from different routes (Note 10).

The usual frequency of administration is once daily but consideration should be given to use of either more frequent or less frequent administration taking into account pharmacokinetic variables (Note 11).

3.3 Pharmaco-/toxicokinetics

It is preferable to have *some* information on pharmacokinetics *before* initiating reproduction studies since this may suggest the need to adjust choice of species, study design and dosing schedules. At this time the information need not be sophisticated nor derived from pregnant or lactating animals.

At the time of study evaluation further information on pharmacokinetics in pregnant or lactating animals may be required according to the results obtained (Note 12).

3.4 Control groups

It is recommended that control animals be dosed with the vehicle at the same rate as test group animals. When the vehicle may cause effects or affect the action of the test substance, a second (sham-or untreated) control group should be considered.

4. Proposed Study Designs—Combination of Studies

All available pharmacological, kinetic, and toxicological data for the test compound and similar substances should be considered in deciding the most appropriate strategy and choice of study design. It is anticipated that, initially, preference will be given to designs that do not differ too radically from those of established guidelines for medicinal products (The most probable option). For most medicinal products the 3-study design will usually be expected. Other designs should be justified.

4.1 The most probable option

The most probable option can be equated to a combination of studies for effects on
- Fertility and early embryonic development
- Pre- and postnatal development, including maternal function
- Embryo-fetal development

4.1.1 Study of Fertility and Early Embryonic Development to Implantation

Aim

To test for toxic effects/disturbances resulting from treatment from before mating (males/females) through mating and implantation. This comprises evaluation of stages A and B of the reproductive process (see 1.2). For females this should detect effects on the oestrus cycle, tubal transport, implantation, and development of preimplantation stages of the embryo. For males it will permit detection of functional effects (e.g. on libido, epididymal sperm maturation) that may not be detected by histological examinations of the male reproductive organs (Note 13).

Assessment of

- maturation of gametes,
- mating behavior,
- fertility,
- preimplantation stages of the embryo,
- implantation.

Animals

At least one species, preferably rats.

Number of Animals

The number of animals per sex per group should be sufficient to allow meaningful interpretation of the data (Note 14).

Administration Period

The design assumes that, especially for effects on spermatogenesis, use will be made of data from repeated dose toxicity studies. Provided no effects have been found that preclude this a premating treatment interval of 2–4 weeks for both males and females can be used (Note 15). Treatment should continue throughout mating to termination of males and at least through implantation for females. This will permit evaluation of

functional effects on male fertility that cannot be detected by histologic examination in repeated dose toxicity studies and effects on mating behavior in both sexes. If data from other studies shows there are effects on weight or histologic appearance of reproductive organs in males or females, or if the quality of examinations is dubious or if there is no data from other studies, then a more comprehensive study should be designed (Note 13).

Mating

A mating ratio of 1:1 is advisable and procedures should allow unequivocal identification of both parents of a litter (Note 16).

Terminal Sacrifice

Females may be sacrificed at any point after mid pregnancy. Males may be sacrificed at any time after mating but it is advisable to ensure successful induction of pregnancy before taking such an irrevocable step (Note 17).

Observations

During study:
- signs and mortalities at least once daily,
- body weight and body weight change at least twice weekly (Note 18),
- food intake at least once weekly (except during mating),
- record vaginal smears daily, at least during the mating period, to determine whether there are effects on the oestrus cycle, mating or precoital time
- observations that have proved of value in other toxicity studies.

At terminal examination:
- autopsy (macroscopic examination) of all adults,
- preserve organs with macroscopic findings for possible histological evaluation; keep corresponding organs of sufficient controls for comparison,
- preserve testes, epididymis, ovary and uterus of unsuccessful animals for possible histological evaluation; keep corresponding organs of sufficient controls for comparison.
- count corpora lutea, implantation sites (Note 18),
- live and dead fetuses where applicable.

4.1.2 Study for effects on pre- and postnatal development, including maternal function

Aim

To detect adverse effects on the pregnant/lactating female and on development of the conceptus and the offspring following exposure of the female from implantation through weaning. Since manifestations of effect induced during this period may be delayed, observations should be continued through sexual maturity (i.e. stages C to F listed in 1.2) (Note 19, 20).

Adverse Effects to be Assessed

- enhanced toxicity relative to that in non-pregnant females,
- pre- and postnatal death of offspring,
- altered growth and development,
- functional deficits in offspring, including behaviour, maturation (puberty) and reproduction (F1).

Animals

At least one species, preferably rats.

Number of Animals

The number of animals per sex per group should be sufficient to allow meaningful interpretation of the data (Note 14).

Administration Period

Females are exposed to the test substance from implantation to the end of lactation (i.e. stages C to E listed in 1.2)

Experimental Procedure

The females are allowed to deliver and rear their offspring to weaning at which time one male and one female offspring per litter should be randomly selected for rearing to adulthood and mating to assess reproductive competence (Note 21).

Observations

During study (for maternal animals):
- signs and mortalities at least once daily,
- body weight and body weight change at least twice weekly (Note 18),
- food intake at least once weekly at least until delivery,
- observations that have proved of value in other toxicity studies,
- duration of pregnancy,
- parturition.

At terminal examination (for maternal animals and where applicable for offspring)
- autopsy (macroscopic examination) of all adults,
- preservation and possibly histological evaluation of organs with macroscopic findings,
- implantations (Note 18)
- abnormalities
- live offspring at birth,
- dead offspring at birth,
- body weight at birth,
- pre- and postweaning survival and growth/body weight (Note 22), maturation and fertility,
- physical development (Note 23),
- sensory functions and reflexes (Note 23),
- behavior (Note 23).

4.1.3 Study for effects on embryo-fetal development

Aim

To detect adverse effects on the pregnant female and development of the embryo and fetus consequent to exposure of the female from implantation to closure of the hard palate (i.e. stages C to D listed in 1.2).

Adverse Effects to be Assessed

- enhanced toxicity relative to that in non-pregnant females,
- embryofetal death,
- altered growth including structural changes.

Animals

Usually, two species: one rodent, preferably rats; one non-rodent, preferably rabbits (Note 6). Justification should be provided when using one species.

Number of Animals

The number of animals should be sufficient to allow meaningful interpretation of the data (Note 14).

Administration Period

The treatment period extends from implantation to the closure of the hard palate (i.e. end of C)—see 1.2.

Experimental Procedure

Females should be killed and examined about one day prior to parturition and fetuses delivered by hysterectomy. All fetuses should be examined for viability and abnormalities. To allow subsequent assessment of the relationship between observations made by different techniques fetuses should be individually identified (Note 24).

When using techniques requiring allocation to separate examination for soft tissue or skeletal changes, it is preferable that 50% of fetuses from each litter be allocated for skeletal examination and the remainder allocated for soft tissue examination. When using fresh microdissection techniques for soft tissue abnormalities - which is the strongly preferred method for rabbits - all fetuses should be examined for both soft tissue and skeletal abnormalities.

Observations

During study (for maternal animals):
- signs and mortalities at least once daily,
- body weight and body weight change at least twice weekly (Note 18),
- food intake at least once weekly, and
- observations that have proved of value in other toxicity studies.

At terminal examination:
- autopsy (macroscopic examination) of all adults,
- preserve organs with macroscopic findings for possible histological evaluation; keep corresponding organs of sufficient controls for comparison,
- count corpora lutea, numbers of live and dead implantations (Note 18),
- individual fetal body weight,
- fetal abnormalities (Note 24),
- appearance of placenta and amniotic fluid.

4.2 Other options

Other strategies, combinations of studies and study designs could be as valid or more valid as the "most probable option" according to circumstances. The key factor is that, in total, they leave no gaps between stages and allow direct or indirect evaluation of all stages of the reproductive process (Note 25).

4.2.1 Combined study design (rodents)

If the dosing period of the fertility study and pre- and postnatal study are combined into a single investigation, this equates to the rearing phase of the Segment 1 study currently recommended by the EC and almost to the two generation study used for food additives and agrochemicals. This comprises evaluation of stages A to F of the reproductive process (see 1.2). If such a study provided clearly negative results at sufficiently high exposure in treated animals no further reproduction studies should be required. Where fetal examinations for structural abnormalities are considered necessary the above test can be supplemented with an embryo-fetal development study (or studies) to make a 2-segment approach (Note 4, 25).

4.2.2 Two study design (rodents)

The simplest two segment design would consist of the fertility study outlined in 4.1.1 and the pre- and postnatal development study outlined in 4.1.2. If the latter provided no indication of prenatal effect at adequate margins above human exposure, the fetal examinations of the embryo-fetal development study (4.1.3) are most unlikely to provide a major change in the assessment of risk.

Alternately, for those uncertain about omission of fetal examinations, female treatment in the fertility study (4.1.1) could be continued through organogenesis and fetuses examined according to the procedures of the embryo-fetal development study (4.1.3). This, combined with the pre- and postnatal study (4.1.2), would provide *all* the examinations required in "the most probable option" but use considerably less animals (Note 4, 25).

5. Statistics

Analysis of the statistics of a study is the means by which results are interpreted. The most important part of this analysis is to establish the relationship between the different variables and their distribution (descriptive statistics), since these determine how groups should be compared. The distributions of the endpoints observed in reproductive tests are usually non normal and extend from almost continuous to the extreme categorical. When employing inferential statistics the tests used should be justified (Note 26).

6. Data Presentation

The key to good reporting is the tabulation of individual values in a clear concise manner to account for every animal that was entered into the study. A reader should be able to follow the history of any individual animal from initiation to termination and should be able to deduce with ease the contribution that the individual has made to any group summary values. Group summary values should be presented in a form that is biologically plausible (i.e. avoid false precision) and that reflects the distribution of the variable. Appendices or tabulations of individual values such as bodyweight, food consumption, litter values should be concise and, as far as possible, consist of absolute rather than calculated values; unnecessary duplication should be avoided. For tabulation of low frequency observations such as clinical signs, autopsy findings, abnormalities etc. it is advisable to group together the (few) individuals with a positive recording. Especially in the presentation of data on structural changes (fetal abnormalities) the primary listing (tabulation) should clearly identify the litters containing abnormal fetuses, identify the affected fetuses in the litter and report all the changes observed in the affected fetus. Secondary listings by type of change can be derived from this, if necessary.

7. Terminology

Besides effects on the reproductive competence of adult animals *toxicity to reproduction* includes:

Developmental toxicity: Any adverse effect induced prior to attainment of adult life. It includes effects induced or manifested in the embryonic or fetal period and those induced or manifested postnatally.

Embryotoxicity, fetotoxicity, embryo-fetal toxicity: Any adverse effect on the conceptus resulting from prenatal exposure, including structural or functional abnormalities or postnatal manifestations of such effects.

Terms like "embryotoxicity", "fetotoxicity" relate to the timepoint/period of induction of adverse effects, irrespective of the time of detection.

One, two or three generation studies are defined according to the number of adult breeding generations directly exposed to the test material. For example, in a one generation study there is direct exposure of the F0 generation and indirect exposure (via the mother) of the F1 generation. In a two generation study there is direct exposure of the F0 generation, indirect and direct exposure of the F1 generation and indirect exposure of the F2 generation. The EC Segment 1 study includes 2 breeding generations but only the F0 generation receives direct treatment.

Body burden: The total internal dosage of an individual arising from the administration of a substance, comprising parent compound and metabolites, taking distribution and accumulation into account.

Note 1 Title

There has been different understanding and use of specific terminology in the three regions, especially "reproduction" and "development". The chairperson of the International Federation of Teratological Societies, therefore, has been asked to supply the correct title for this guideline. The title will be adapted accordingly.

Note 2 (1.1) Terminology Kinetics

It is the opinion of the Safety working group that "Pharmacokinetics" should be used consistently throughout this guideline. However, consistency will have to be obtained with the draft guideline on "Toxicokinetics". The terminology proposed in that guideline will have to be introduced in this guideline.

Note 3 (1.1) Scientific flexibility

These guidelines are not mandatory rules, they are a starting point rather than an endpoint. They provide a basis from which an investigator can devise a strategy for testing according to available knowledge of the test material and the state of the art. For encouragement some alternative test designs have been mentioned in this document but there are others that can be sought out or devised. In devising a strategy the primary objective should be to detect and bring to light any indication of toxicity to reproduction. Only by knowing and understanding the situations (exposures) in which a toxic effect may be elicited, can assured presumptions be made of the situations in which toxicity is unlikely to occur.

Fine details of study design and technical procedures have been omitted from the text. Such decisions rightly belong in the field of the investigator since a technique that may be suitable for one laboratory may not be suitable in another. The investigator needs to utilise staff and resources to do the best he or she can achieve and should know how to do this better than any outsider; human attributes of attitude, ability and consistency are more important than material facilities. For necessary compliance to GLP, reference is made to such regulations.

Note 4 (1.3) First pass and secondary testing

To a greater or lesser degree *all* first pass (guideline) tests are apical in nature, i.e., an effect on one endpoint may have several different origins. A reduced litter size at birth may be due to a reduced ovulation rate (corpora lutea count), higher rate of preimplantation deaths, higher rate of postimplantation deaths or immediate postnatal deaths. In turn these deaths may be the consequence of an earlier physical malformation that can no longer be observed due to subsequent secondary changes and so on. Particularly for effects with a natural low frequency among controls, discrimination between treatment induced and coincidental occurrence is dependent upon association with other types of effect. A toxicant usually induces more than one type of effect in a dose dependent manner. For example, induction of malformation is almost invariably associated with increased embryonic death and an increased incidence of less severe structural changes. Given an effect on one endpoint secondary investigations for possible associations should be considered i.e. the nature, scope and origins of the substance's toxicity should be characterised. Characterisation should also include identification of dose-response relationships to facilitate risk assessment; this is different from the situation in first pass tests where the presence or absence of a dose-response assists discrimination between treatment related and coincidental differences.

Note 5 (1.3) Preliminary studies

At the time most reproduction studies are planned or initiated there is usually information available from acute and repeated dose toxicity studies of at least one month duration. This information often is quite sufficient and appropriate to allow selection of dosages for reproductive studies considering that reproductive toxicity is judged relative to other toxicities. Nevertheless, for a variety of motives many investigators prefer to conduct specific, preliminary (range finding) studies, especially in pregnant females. The need for such studies should be carefully considered.

Note 6 (2.1) Selection of species and strains

In choosing an animal species and strain for reproductive toxicity testing care should be given to select a relevant model. If it can be shown that the species selected is a relevant model for the human a single species can be sufficient. Advantages and disadvantages of species (strains) should be considered in relation to the substance to be tested and to the selected study design. Selection of the species and strain used in other toxicity studies may avoid the need for additional preliminary studies.

All species and strains have their drawbacks, for example:

Rats: sensitivity to sexual hormones, unsuitable for dopamine agonists due to dependence on prolactin as the primary hormone for establishment and maintenance of early pregnancy, highly susceptible to non-steroidal anti-inflammatory drugs in late pregnancy.

Mice: fast metabolic rate, stress sensitivity, malformation clusters, small fetus size.

Rabbits: often lack of pharmacokinetic and toxicity data, susceptibility to some antibiotics and to disturbance of the alimentary tract, clinical signs can be difficult to interpret.

Guinea pigs: often lack of pharmacokinetic and toxicity data, susceptibility to some antibiotics and to disturbance of the alimentary tract, long fetal period, insufficient historical background data.

Domestic and/or mini pigs: malformation clusters with variable background rate, large amounts of compound required, large housing necessary, insufficient historical background data.

Ferrets: seasonal breeder unless special management systems used (success highly dependent on human/animal interaction), insufficient historical background data.

Hamsters: intravenous route difficult if not impossible, can hide doses in the cheek pouches and can be very aggressive, sensitive to intestinal disturbance, overly sensitive teratogenic response to many chemicals.

Dogs: seasonal breeders, inbreeding factors, insufficient historical background data.

Non-human primates: pharmaco- and toxicokinetically they can differ from humans as much as other species, insufficient historical background data, often numbers too low for detection of risk. They are best used, when the objective of the study is to characterise a relatively certain reproductive toxicant, rather than detect a hazard.

All species have their advantages. Rats and to a lesser extent mice, are good, general purpose models; the rabbit has been somewhat neglected as a "non-rodent" species for repeated dose toxicity and other reproduction studies than embryotoxicity testing. It has attributes that would make it a useful model for fertility studies, especially male fertility. For both rabbits and dogs (which are often used as a second species for chronic toxicity studies) it is feasible to obtain semen samples without resorting to painful techniques (electro ejaculation) for longitudinal semen analysis. Most of the other species are not good general purpose models and probably are best used for very specific investigations.

Note 7 (2.2) Uses of other test systems than whole animals

Other test systems have been developed and used in preliminary investigations ("pre-screening" or priority selection) and secondary testing.

For preliminary investigation of a range of analogue series of substances it is essential that the potential outcome in whole animals is known for at least one member of the series to be studied (by inference, positive effects are expected). With this strategy substances can be selected for higher level testing.

For secondary testing or further substance characterisation other test systems offer the possibility to study some of the observable developmental processes in detail, e.g. to reveal specific mechanisms of toxicity, to establish concentration-response relationships, to select 'sensitive periods', or to detect effects of defined metabolites.

Note 8 (3.1) Selection of dosages

The high dose should be based on drug specific toxicity. In cases where no target organ is identified, decreases in body weight gain and food consumption, clinical signs, hematology, clinical chemistry, etc., may be appropriate indices of toxicity. With rare exceptions, there will be little need to exceed a limit dosage of 1 g/kg/day. Using similar doses in the reproductive toxicity studies as in the one month toxicity study will allow comparison with the repeated dose studies, and interpretation of any potential effects on fertility in context with general systemic toxicity.

Factors limiting the high dosage could include:

- reduction in bodyweight gain.
- increased bodyweight gain, particularly when related to perturbation of homeostatic mechanisms.
- exaggerated pharmacological response, which may or may not be reflected as marked clinical reactions (e.g., sedation, convulsions).
- the physico-chemical properties of the test substance or dosage formulation which, allied to the route of administration, may impose practical limitations in the amount that can be administered.
- pharmaco-/toxicokinetics, i.e., there is little point in increasing administered dosage if it does not result in increased plasma or tissue concentration or if it prompts divergence into secondary pathways that would not be encountered in therapeutic usage.

Note 9 (3.1) Determination of dose-response relationships

For many of the variables in reproduction studies the power to discriminate between random variation and treatment effect is poor and the presence or absence of a dosage related trend can be a critical means of determining the probability of a treatment effect. It has to be kept in mind that in these studies, dose-responses usually are steep, and wide intervals between doses would be inadvisable. If an analysis of dose-response relationships for the effects observed is attempted in a single study, it is recommended to use at least three dose levels and appropriate control groups. If in doubt, a fourth dose group should be added to avoid excessive dosage intervals. Such a strategy should provide a "no observed adverse effect level" for reproductive aspects. If not, the implication is that the test substance merits a greater depth of investigation and further studies.

Note 10 (3.2) Exposure by different routes of administration

If it can be shown that one route provides a greater body burden, e.g. area under the curve (AUC), there seems little reason to investigate routes that would provide a lesser body burden or which present severe practical difficulties (e.g. inhalation). Before designing new studies for a new route of administration existing data on pharmaco- and toxicokinetics should be used to determine the necessity of another study.

Note 11 (3.2) Timing conventions

In this guideline the convention for timing of pregnancy is to refer to the day that a sperm positive vaginal smear and/or plug is observed as day 0 of pregnancy even if mating occurs overnight. Unless shown otherwise it is assumed that, for rats, implantation occurs on day 6 of pregnancy, closure of the hard palate occurs on day 17 of pregnancy, and parturition most commonly occurs on day 22 of pregnancy. For mice closure of the hard palate is on day 15, and for rabbits on day 20. For rabbits where pregnancy is timed from artificial insemination or coitus the convention of using day 0 is more accurate than for rats because the rabbit is an induced ovulator.

Other conventions for rodents are equally acceptable but **must** be defined in reports. Also, the investigator must be consistent in different studies to assure that no gaps in treatment occur. It is an advisable precaution to provide an overlap of at least one day in the exposure period of related studies.

The accuracy of the time of mating should be specified since this will affect the variability of fetal and neonatal parameters.

Similarly, for reared litters, the day offspring are born will be considered as postnatal or lactation day 0 unless otherwise specified. However, particularly in respect of developmental landmarks, reference to a postcoital time frame may be useful.

Note 12 (3.3) Pharmaco-/toxicokinetics in pregnant animals

Kinetic investigations in pregnant and lactating animals may pose some problems due to rapid changes in physiology. It is best to consider this as a two or three phase approach. In planning studies kinetic data (often from non-pregnant animals) provide information on the general suitability of the species, and can assist in deciding study designs and choice of dosage. During a study kinetic investigations can provide assurance of accurate dosing or indicate marked deviations from expected patterns. In evaluating studies the kinetic information required depends upon the results obtained.

Note 13 (4.1.1) Premating treatment

The design of the fertility study, especially the reduction in the premating period for males, may seem to be a radical departure from existing guidelines but is based on evidence accumulated and reappraisal of the basic research on the process of spermatogenesis that originally prompted the demand for a prolonged premating treatment period. In brief, compounds inducing selective effects on male reproduction are rare; mating with females is an insensitive means of detecting effect on spermatogenesis; good pathological and histopathological examination of the male reproductive organs provides a more sensitive and quicker means of detecting effects on spermatogenesis; compounds affecting spermatogenesis almost invariably affect post meiotic stages; there is no conclusive example of a male reproductive toxicant the effects of which

could be detected only by dosing males for 9–10 weeks and mating them with females.

Information on potential effects on spermatogenesis can be derived from repeated dose toxicity studies. This allows the investigations in the fertility study to be concentrated on other, more immediate, causes of effect. It is noted that, to encompass one full cycle of spermatogenesis in rats, 63 days of drug administration is needed (see Note 15). When the available evidence, or lack of it, suggests that the scope of investigations in the fertility study should be increased, or extended from detection to characterisation, appropriate studies should be designed to further characterise the effects (see also Note 15).

Note 14 (4.1.1, 4.1.2, 4.1.3) Number of animals

There is very little scientific basis underlying specified group sizes in past and existing guidelines nor in this one. The numbers specified are educated guesses governed by the maximum study size that can be managed without undue loss of overall study control. This is indicated by the fact that the more expensive the animal is to obtain or keep, the smaller the group size required. Scientifically and statistically at least the same group size should be required for all species and there is a case for using larger group sizes for less frequently used species such as primates.

It should also be made clear that the numbers required depend on whether the group is expected to demonstrate an effect. For a positive effect few animals (1–5) are required, to presume the absence of an effect the number required varies according to the variable (endpoint) being considered, its prevalence in control populations (rare or categorical events) or dispersion around the central tendency (continuous or semi-continuous variables). For all but the rarest events (such as malformations, abortions, total litter loss), evaluation of between 16–20 litters tends to provide a degree of consistency between studies. Below 16 litters per evaluation, between study results become inconsistent, above 20–24 litters per group consistency and precision is not greatly enhanced. These numbers relate to evaluation. If groups are subdivided for different evaluations the number of animals starting the study should be doubled. Similarly, in studies with 2 breeding generations, 16–20 litters would be required for the final evaluation of the litters of the F1 generation so, to allow for natural wastage, the starting group size of the F0 generation would need to be in the order of 28–32 animals.

Note 15 (4.1.1) Research

ICH participants will cooperate in a research program to determine the optimum parameters to be used in animal male fertility studies to ensure their relevance.

Reference is given to the paper by Takayama.

Note 16 (4.1.1) Mating

Mating ratios: When both sexes are being dosed or of equal consideration in separate male and female studies the preferred mating ration is 1:1 since this is the safest option in respect of obtaining good pregnancy rates and avoiding incorrect analysis and interpretation of results. When there is special emphasis on the male (usually a secondary stage investigation) and it is being mated to untreated females then the mating ratio may be increased (1 male to 3–5 females) but the male, not the female, should be used as the basic sample unit for comparison of groups. Similarly, higher mating ratios may be used when untreated (stock) males are being used to provide pregnant females for a study such as 4.1.2 or 4.1.3. It is important that females mated to the same male are distributed evenly across the control and test groups and that records of male/female matings are kept. If this is not done then coincidental effects of male origin may be inadvertently attributed to treatment of the female.

Mating period and practices: Most laboratories would use a mating period of between 2–3 weeks, some remove females as soon as a positive vaginal smear or plug is observed whilst others leave the pairs together; some will place apparently unimpregnated females with another male. This latter procedure can lead to confusion as to true parentage of the litter and miscalculation of precoital time. Most rats will mate within the first 5 days of cohabitation (i.e. at the first available estrus), but in some cases females may become pseudopregnant. Leaving the female with the male for about 20 days allows these females to restart estrus cycles and become pregnant.

Note 17 (4.1.1) Terminal sacrifice

When exposure of the females ceases at implantation, termination of females between days 13–15 of pregnancy is adequate to characterise effects on fertility or reproductive function, e.g. to differentiate between implantation and resorption sites. In general, it is not thought necessary in a fertility study to sacrifice females at day 20/21 of pregnancy in order to gain information on late embryo loss, fetal death, and structural abnormalities. Exceptions might be "secondary stage" characterisation studies of a genotoxin or material with a prolonged retention time.

It would be advisable to delay sacrifice of the males until the outcome of mating is known. In the event of an equivocal result males could be mated with untreated females to ascertain their fertility or infertility. The males treated as part of study 4.1.1 may also be used for evaluation of toxicity to the male reproductive system if dosing is continued beyond mating and sacrifice delayed.

Note 18 (4.1.1, 4.1.2, 4.1.3) Observations

Daily weighing of females during pregnancy is advisable since it greatly aids overall study control. Weighing an animal more frequently than twice weekly during periods other than pregnancy (premating, mating, lactation) may also be advisable for some compounds.

For apparently non-pregnant rats or mice, but not rabbits, ammonium sulphide staining of the uterus might be useful to identify peri-implantation death of embryos.

Note 19 (4.1.2) Treatment of offspring

Consequent to derivation from existing guidelines for medicines this guideline does not fully cover exposures from weaning through puberty, nor does it deal with the possibility of reduced reproductive life span.

To detect adverse effects for medicinal products that may be used in infants and juveniles, special studies (case by case designs) involving direct treatment of offspring, at ages to be specified, should be considered.

Note 20 (4.1.2) Separate embryotoxicity and peri-postnatal studies

If a pre- and postnatal study is separated into two studies, one covering the embryonic period the other the fetal period, parturition, and lactation, postnatal evaluation of offspring is required in both studies.

Note 21 (4.1.2) F1-animals

For practical reasons as well as for the safe handling of animals separate animals may be used for different tests.

Note 22 (4.1.2) Reduction of litter size

If culling is performed, it should be clearly stated and justified.

Note 23 (4.1.2) Physical development, sensory functions, reflexes, and behaviour

The best indicator of physical development is bodyweight. Achievement of preweaning landmarks of development such as pinna unfolding, coat growth, incisor eruption etc. is highly correlated with body weight. In respect of time, developmental landmarks and bodyweight are better related to postcoital time rather than postnatal time. Reflexes, surface righting, auditory startle, surface righting, and response to light are also dependent on physical development. The one proven value of including such preweaning observations in a study is that they promote more frequent and regular general observation of offspring. If the investigator wishes to observe landmarks of development then, rather than recording many different landmarks inadequately (i.e. single day examination only), it may be better to select 3–5 in a sequence from birth to weaning (e.g. surface righting, incisor eruption, auditory startle, eye opening, air righting). Recording should start just before the anticipated day of occurrence and should continue until all offspring have been accounted for. Alternatively a starting day based on a 50% tile of occurrence in controls could be chosen. The overall selection of landmarks should provide a situation in which every pup is handled and inspected on almost every day from birth to weaning. If "single day" examinations are used the investigator should select a time when only 50% of offspring are expected to reach attainment.

Two postweaning landmarks of development that are advised are vaginal opening of females and cleavage of the balanopreputial gland of males. The latter is associated with increasing testosterone levels whereas testis descent is not. These landmarks indicate the onset of sexual maturity and it is advised that bodyweight be recorded at the time of attainment to

determine whether any differences from control are specific or related to general growth.

Functional tests: To date, functional tests have been directed almost exclusively to behavior. Even though a great deal of effort has been expended in this direction it is not possible to recommend specific test methods. Investigators are encouraged to find methods that will assess sensory functions, motor activity, learning and memory.

Note 24 (4.1.3) Individual identification and evaluation of fetuses

It must be possible to relate all kind of findings by different techniques (body weight, external inspection, visceral and/or skeletal examinations) to single specimen in order to detect patterns of abnormalities.

The examination of mid and low dose fetuses for visceral and/or skeletal abnormalities may not be necessary where the evaluation of the high dose and the control groups did not reveal any relevant differences. It is advisable, however, to store the fixed specimen for possible later examination. If fresh dissection techniques are normally used, difficulties with later comparisons involving fixed fetuses should be anticipated.

Note 25 (4.2) Examples for choosing other options

For compounds causing no lethality at 2 g/kg and no evidence of repeated dose toxicity at 1 g/kg (e.g. some antibiotics) conduct of a single 2 generation study with one control and 2 test groups (0.5 and 1.0 g/kg) would seem sufficient. However, it might pose the question as to whether the correct species had been chosen or whether the compound was an effective medicine.

For compounds that may be given as a single dose, once in a lifetime, (e.g. diagnostics, medicines used in operations) it may be impossible to administer repeated dosages more than twice the human therapeutic dosage for any length of time. A reduced period of treatment allowing a higher dose would seem more appropriate. For females considerations of human exposure suggest little or no need for exposures beyond the embryonic period.

For dopamine agonists or compounds reducing circulating prolactin levels female rats are poor models; the rabbit would probably make a better choice for all the reproductive toxicity studies, but it does not appear to have been attempted. This also applies to other types of compound when the rabbit shows a pattern of metabolism considerably closer to humans than the rat.

For drugs where alterations in plasma kinetics are seen following repeated administration, the potential for adverse effects on embryo-fetal development may not be fully evaluated in studies according to 4.1.3. In such cases it may be desirable to extend the period of drug administration to females in a 4.1.1 study to day 17. With sacrifice at term, both fertility and embryo-fetal development can be assessed.

Note 26 (5.) Inferential statistics

"Significance" tests (inferential statistics) can be used only as a support for the interpretation of results. The interpretation itself must be based on biological plausibility. It is unwise to assume that a difference from control values is not biologically relevant simply because it is not "statistically significant". To a lesser extent it can be unwise to assume that a "statistically significant" difference must be biologically relevant. Particularly for low frequency events (e.g. embryonic death, malformations) with one sided distributions, the statistical power of studies is low. When using "significance" tests as experimental units of comparison should be considered: the litter, not the individual conceptus, the mating pair, when both sexes are treated, the mating pair of the parent generation in a two generation study.

Dated: April 12, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–8942 Filed 4–13–93; 8:45 am]

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federal register

Friday
April 16, 1993

Part IX

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonization; Studies in Support of Special Populations; Geriatrics; Draft Guideline; Availability; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93D–0138]

International Conference on Harmonization; Studies in Support of Special Populations; Geriatrics; Draft Guideline; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline regarding studies in support of the use of drugs in geriatric populations. This draft guideline was prepared by the Efficacy Expert Working Group of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to reflect sound scientific principles for testing drugs in geriatric populations.

DATES: Written comments by May 17, 1993.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding the draft guideline: Mary Doug Tyson, Center for Drug Evaluation and Research (HFD–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2894.

Regarding the ICH: Janet Showalter, Office of Health Affairs (HFY–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Community, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industry Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, the U.S. Food and Drug Administration, and the U.S. Pharmaceutical Manufacturers Association. In addition, the ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the organizing bodies and the IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

At a meeting held on September 16, 1992, the ICH Steering Committee agreed that the draft tripartite guideline entitled "Studies in Support of Special Populations: Geriatrics" should be made available for comment. The draft guideline will be made available for comment by the European Community and Japan, as well as by FDA, in accordance with their consultation procedures. The draft guideline is intended to be consistent with FDA's existing geriatric guideline. FDA is publishing the guideline to facilitate the ICH process; after the comments are analyzed and the guideline revised as necessary, FDA will determine whether it will adopt the tripartite guideline. The guideline addresses harmonization in relation to medicines for the geriatric population, which is expected to increase significantly in the near future in Europe, Japan, and the United States. The use of drugs in the geriatric population requires special consideration due to the frequent occurrence of underlying diseases, concomitant drug therapy, and the consequent risks of drug interaction.

Interested persons may, on or before May 17, 1993, submit written comments on the draft guideline to the Dockets Management Branch (address above). Two copies are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will not extend the comment period on this notice because the agency must respond to the ICH in early June.

The text of the draft guideline follows:

Studies in Support of Special Populations: Geriatrics Harmonised Guidelines

I. Statement of Purpose

It is important to ensure that clinical testing programs are carried out according to harmonised guidelines based on agreed ethical and scientific principles, so that the international development of valuable innovative drugs is achieved with maximum efficiency. Harmonisation in relation to medicines for geriatric populations is an important issue because the total population of the elderly will increase significantly in the coming years in Europe, Japan and the USA. The use of drugs in this population requires special consideration due to the frequent occurrence of underlying diseases, concomitant drug therapy and the consequent risk of drug interaction.

II. General Principle

Drugs should be studied in all age groups, including the elderly, for which they will have significant utility. Patients entering clinical trials should be reasonably representative of the population that will be later treated by the drug.

III. Scope of Guideline

This guideline is directed principally toward New Molecular Entities that are likely to have significant use in the elderly, either because the disease intended to be treated is characteristically a disease of aging (e.g., Alzheimer's disease) or because the population to be treated is known to include substantial numbers of geriatric patients (e.g., hypertension). The guideline applies also to novel formulations and new combinations of established medicinal products when there is specific reason to expect that conditions common in the elderly (e.g., renal or hepatic impairment, impaired cardiac function, concomitant illnesses or concomitant medications) are likely to be encountered and are not already dealt with in current labelling. It likewise applies when the novel formulation or new combination is likely to alter the geriatric patient's response (with regard to either safety/tolerability or efficacy) compared with that of the non-geriatric patient in a way different from previous formulations. The guideline also applies to new uses that have significant potential applicability to the elderly.

It is recommended that exemptions from the guideline be determined in advance either by sponsors or by the sponsor and drug registration authorities, based, e.g., on estimates of the disease prevalence by age or through examination of the age distribution of usage for other drugs of the same class or drugs used for the same indication.

IV. Definition of the Population

The geriatric population is arbitrarily defined, for the purpose of this guideline, as comprising patients aged 65 years or older. It is important, however, to seek patients in the older age range, 75 and above, to the extent possible. Protocols should not ordinarily include arbitrary upper age cutoffs. It is also important not to exclude unnecessarily patients with concomitant

illnesses; it is only by observing such patients that drug-disease interactions can be detected. The older the population likely to use the drug, the more important it is to include the very old.

V. Clinical Experience

Geriatric patients should be included in the Phase 3 database (and in Phase 2, at the sponsor's option) in meaningful numbers. The geriatric subpopulation should be represented sufficiently to permit the comparison of drug response in them to that of younger patients. For drugs used in diseases not unique to, but present in, the elderly, a minimum of 100 patients would usually allow detection of clinically important differences. For drugs to treat relatively uncommon diseases, smaller numbers of the elderly would be expected. Where the disease to be treated is characteristically associated with aging (e.g., Alzheimer's disease) it is expected that geriatric patients will constitute the major portion of the clinical database.

The overall database of the dossier should be examined for the presence of age-related differences, e.g., in adverse event rates, in effectiveness, and in dose-response. If these relatively crude overview analyses show important differences, further evaluation may be needed.

The geriatric data used in the overview can come either from the inclusion of elderly patients in all or most of the main Phase 2/3 studies or from studies conducted exclusively in geriatric patients, at the sponsor's option. Inclusion of both groups in the same studies has the advantage of allowing direct comparisons of younger and older patients using data collected in similar ways. Such comparisons are more difficult when separate studies of young and old patients are used. Certain assessments, however, e.g., studies of cognitive function, require special planning and can be accomplished in separate studies.

VI. Pharmacokinetic Studies

Most of the recognized important differences between younger and older patients have been pharmacokinetic differences, often related to impairment of excretory (renal or hepatic) function or to drug-drug interactions. It is important to determine whether or not the pharmacokinetic behavior of the drug in elderly subjects or patients is different from that in younger adults and to characterize the effects of influences, such as abnormal renal or hepatic function, that are more common in the elderly even though they can occur in any age group. Information regarding age-related differences in the pharmacokinetics of the drug can come, at the sponsor's option, either from a Pharmacokinetic Screen (as described subsequently) or from formal pharmacokinetic studies, in the elderly and in patients with excretory functional impairment.

A. Formal Pharmacokinetic Studies

Formal PK studies can be done either in healthy geriatric subjects or in patient volunteers with the disease to be treated by the drug.

The initial PK study can be a pilot trial of limited size conducted under steady-state conditions to look for sizable differences between older and younger subjects or patients. A larger, single-dose PK study of sufficient size to permit statistical comparisons between geriatric and younger subjects' or patients' pharmacokinetic profiles is also acceptable.

In either case, if large (i.e., potentially medically important) age-related differences are found, the initial PK study may need to be followed by a multiple-dose PK study of sufficient size to permit statistical comparisons (geriatric vs. younger) at steady-state.

B. Pharmacokinetic Screening Approach

Sponsors may opt, instead of conducting a separate PK evaluation of the elderly, to utilize a Pharmacokinetic Screen in conjunction with the main Phase 3 (and Phase 2, if the sponsor wishes) clinical trials program. This screening procedure involves obtaining, under steady-state conditions, a small number (one or two) of drug blood level determinations at "trough" (i.e., just prior to the next dose) or other defined times from sufficient numbers of Phase 2/3 clinical trials patients, geriatric and younger, to detect age-associated differences in pharmacokinetic behavior, if they are present. It is important to record time of dosing prior to blood concentration measurements, and relation of dosing to meals, and to examine the influence of demographic and disease factors, such as gender renal function, presence of liver disease or heart disease, body size and composition, and concomitant illnesses.

Small differences are unlikely to be of medical importance. Where the screen detects large differences, formal pharmacokinetic studies may be indicated as a result, unless the screen's results are sufficiently informative.

The advantage of a Pharmacokinetic Screen is that it can assess the effects not only of age itself, but of other factors associated with age (altered body composition, other drugs, concomitant illness) and their interactions.

VII. Pharmacokinetics in Renally or Hepatically Impaired Patients

Renal impairment is an aging-associated finding that can also occur in younger patients. Therefore, it is a general principle, not specific to these guidelines, that drugs excreted (parent drug or active metabolites) significantly through renal mechanisms should be studied to define the effects of altered renal function on their pharmacokinetics. Such information is needed for drugs that are the subject of this guideline but it can be obtained in younger subjects with renal impairment.

Similarly, drugs subject to significant hepatic metabolism and/or excretion, or that have active metabolites, may pose special problems in the elderly. Pharmacokinetic studies should be carried out in hepatically-impaired young or elderly patient volunteers.

If a Pharmacokinetic Screen approach is chosen by the sponsor (Section VI, see above), and if patients with documented renal impairment or hepatic impairment (depending on the drug's elimination pattern) are included and the results indicate no medically important pharmacokinetic difference, that information may be sufficient to meet this Geriatric Guideline's purpose.

VIII. Pharmacodynamic/Dose Response Studies

The number of age-related pharmacodynamic differences (i.e., increased or decreased therapeutic response, or side effects, at a given plasma concentration of drug) discovered to date is too small to necessitate dose response or other pharmacodynamic studies in geriatric patients as a routine requirement. Separate studies are, however, recommended in the following situations:

- Sedative/hypnotic agents and other psychoactive drugs or drugs with important CNS effects, such as sedating antihistamines
- Where subgroup comparisons (geriatric versus younger) in the Phase 2/3 clinical trials database indicate potentially medically significant age-associated differences in the drug's effectiveness or adverse reaction profile, not explainable by PK differences

IX. Drug-Drug Interaction Studies

Such interactions are of particular importance to geriatric patients, who are more likely to be using concomitant medications than younger patients, but of course are not limited to this age group. Therefore it is general principle, not specific to these guidelines, that in cases where the therapeutic range (i.e., range of toxic to therapeutic doses) of the drug or likely concomitant drugs is narrow, and the likelihood of the concomitant therapy is great, that specific drug-drug interaction studies be considered. The studies needed must be determined case-by-case, but the following are ordinarily recommended:

- Digoxin and oral anticoagulant interaction studies, because so many drugs alter serum concentrations of these drugs, they are widely prescribed in the elderly, and they have narrow therapeutic ranges
- For drugs that undergo extensive hepatic metabolism, determination of the effects of hepatic-enzyme inducers (e.g., phenobarbital) and inhibitors (e.g., cimetidine)
- For drugs metabolized by cytochrome P–450 enzymes, it is critical to examine the effects of known inhibitors, such as quinidine (for cytochrome P–450 2D6) or ketoconazole and macrolide antibiotics (for drugs metabolized by cytochrome P–450 3A4.) There is a rapidly growing list of drugs that can interfere with other drugs' metabolism, and sponsors should remain aware of it.
- Interaction studies with other drugs that are likely to be used with the test drug (unless important interactions have been ruled out by a Pharmacokinetic Screen)

Dated: April 12, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–8943 Filed 4–13–93; 8:45 am]

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federal register

Friday
April 16, 1993

Part X

Department of Health and Human Services

Food and Drug Administration

International Conference on Harmonization; Submitting Documentation for the Stability of Human Drugs; Draft Guideline; Availability; Notice

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93D–0139]

International Conference on Harmonization; Submitting Documentation for the Stability of Human Drugs; Draft Guideline; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a draft guideline regarding the submission of documentation for the stability testing of human drugs. This draft guideline was prepared by the Quality Expert Working Group of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guideline is intended to reflect sound scientific principles for stability testing of drugs.

DATES: Written comments by May 17, 1993.

ADDRESSES: Submit written comments on the draft guideline to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Charles Kumkumian, Center for Drug Evaluation and Research (HFD–100), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4330; or Roger Williams, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–295–8340.

SUPPLEMENTARY INFORMATION: In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for drug development.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Community, Japan, and the United States. The six ICH sponsors are the European Commission, the European Federation of Pharmaceutical Industry Associations, the Japanese Ministry of Health and Welfare, the Japanese Pharmaceutical Manufacturers Association, FDA, and the U.S. Pharmaceutical Manufacturers Association. In addition, the ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the organizing bodies and IFPMA, as well as observers from the World Health Organization, the Canadian Health Protection Branch, and the European Free Trade Area.

At a meeting held on March 23 and 24, 1992, the ICH Steering Committee agreed that the draft tripartite guideline entitled "Draft Tripartite Guideline for the Stability Testing of New Drug Substances and Products" should be made available for comment. The draft guideline will be made available for comment by the European Community and by Japan, as well as by FDA, in accordance with their consultation procedures. The draft guideline addresses harmonization of stability testing, which is used to establish how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light, and which enables recommended storage conditions, retest periods, and shelf lives to be established.

FDA is publishing the draft guideline to facilitate the ICH process. This tripartite document, however, contains language and positions with which FDA does not agree and thus does not embody FDA's current position on these issues. The issues on which FDA disagrees are addressed in FDA's preface to the draft stability guideline. After the comments are reviewed and analyzed, FDA will reconsider its position as appropriate.

Interested persons may, on or before May 17, 1993, submit written comments on the draft guideline to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit single copies. The draft guideline and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will not extend the comment period on this notice because the agency must respond to ICH in early June 1993.

The text of the draft guideline follows:

Preface

Tripartite Guideline for Stability Testing of New Drug Substances and Products/Draft Number 3 (April 1992).

Attached for public comment is the text of the *Tripartite Guideline for Stability Testing of New Drug Substances and Products/Draft Number 3 (Tripartite Guideline).* This guideline was developed by the Expert Working Group (Quality) of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). Participants in the ICH process include representatives from: (1) The U.S. Food and Drug Administration (FDA); (2) the Ministry of Health and Welfare, Government of Japan; (3) the Commission of the European Communities (EC); (4) the U.S. Pharmaceutical Manufacturers Association (PMA); (5) the Japanese Pharmaceutical Manufacturers Association (JPMA); (6) the European Federation of Pharmaceutical Industries' Associations (EFPIA).

The tripartite guideline is intended to provide internationally accepted regulatory standards for stability testing of new drug substances and drug products. Therefore, upon agreement by the six parties participating in the ICH process, this guideline contains stability test protocols that would be acceptable for developing the stability data to be submitted in drug premarket approval applications. That is, if FDA adopts this guideline it would be applicable to stability test data in new drug applications (NDA's).

Application of the ICH stability protocol to justify the U.S. Pharmacopoeia (USP) controlled room temperature (CRT) label claim for a marketed drug product is, among other things, cause for FDA concern. These reservations are consistent with FDA's comments on previous versions of the tripartite guideline. In addition, FDA has serious concerns about several related concepts in the current draft guideline text. A brief summary of the agency's reservations concerning the stability protocol is given below, followed by a discussion of the related chemistry issues.

A critical element of the tripartite guideline is the selection of 25 °C as the temperature to be used for the long-term stability storage test temperature that would support a CRT storage statement on pharmaceutical products. The selection of 25 °C is based on a climatic zone concept, including a generalized application of the Arrhenius relationship, and the assumption that the United States, Japan, and EC countries are located in geographic regions of the world defined by climatic zones I and II.

Early in the ICH process, FDA raised concerns associated with long-term testing at 25 °C to support USP label storage conditions for CRT (15 to 30 °C). FDA is concerned that such an approach may not be adequate to demonstrate that the drug is safe and

effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling by assuring its identity, strength, quality, and purity when stored over its expiration dating period.

FDA scientists are critical of the premise that stability testing should assess product quality and performance characteristics only under conditions that correspond to the environmental conditions of climatic zones I and II. Temperatures in regions with significant populations in the United States, territories of the United States, and other nations of commerce are defined by climatic zones III and IV. Recent literature reports have suggested that 31 °C is the recommended long-term stability testing temperature for climatic zones III and IV. In addition, concepts of the Arrhenius equation, which form the basis of the climatic zone approach, do not provide a reliable method for predicting the chemical and physical behavior of a complex dosage form. Physical properties, such as dissolution, appearance and hardness, would reasonably be expected to change upon storage over a product's expiration dating period.

From a regulatory perspective, FDA has maintained in ICH negotiations that stability studies should be carried out at the highest temperature claimed on the label to be acceptable for storage. USP defines a temperature range of 15 to 30 °C as CRT. Therefore, for marketed products that will bear the USP CRT label claim, long-term stability studies should be performed at 30 °C.

In addition to the problems associated with testing at 25 °C to support a CRT label claim, FDA is critical of a number of other positions reflected in the proposed tripartite guideline. The guideline requires detailed analysis of accelerated testing data (6 months at 40 °C with 75 percent relative humidity (RH)) to determine if a significant change occurs in a drug substance or drug product stored under the accelerated test conditions. Yet, the guideline does not define significant change, and FDA recognizes the challenge in achieving an international consensus on a definition. Furthermore, if a significant change occurs in the accelerated testing data, testing for at least 6 months at a third temperature station is called for in the guideline (30 °C/60 percent RH). A problematic aspect of the third temperature station that adds to the ambiguity and complexity of the protocol is the mechanism for evaluating test results at this station. Furthermore, the tripartite guideline does not discuss the interpretation and subsequent impact of the 30 °C data relative to the long-term 25 °C stability data. This omission is particularly significant because it makes calculation of an expiration dating period ambiguous if a drug product demonstrates different stability behavior at 25 °C and 30 °C. Resolution of this ambiguity is not addressed in the guideline. Rather than harmonizing stability testing standards based on simplified procedures, the guideline as currently drafted would foster confusion.

FDA has proposed to ICH an international stability testing protocol that would resolve the important deficiencies discussed above. The protocol would be based on long-term testing at 30 °C (at not less than 60 percent RH) with accelerated testing for 3 months at 40 °C (at not less than 75 percent RH). In the United States, this protocol would support a USP CRT label claim of 15 to 30 °C.

Other recommended revisions to the tripartite guideline include: (1) Stability test data obtained from laboratory batches would not be acceptable as primary data for determination of an expiration dating period; (2) full stability data should be submitted from three batches, not two, at the time of NDA submission; (3) data from all marketed container/closure systems, not just the most sensitive, should be submitted in an application; (4) formal statistical analysis should be applied to all long term data; and (5) that the phrase "three month weighted average" under temperature fluctuations should be deleted.

Tripartite Guideline for the Stability Testing of New Drug Substances and Products

Draft Number 3

April 1992

Introduction

Preamble

The following guideline sets out the stability testing requirement for a Registration Application within the three areas of the EC, Japan and the USA. It does not seek necessarily to cover the testing that may be required for registration in or export to other areas of the world.

The guideline seeks to exemplify the core stability data package required for new drug substances and products. It is not always necessary to follow this when there are scientifically, justifiable reasons for using alternative approaches.

The guideline provides a general indication on the requirements for stability testing, but leaves sufficient flexibility to encompass the variety of different practical situations demanded with regards to specific situations and characteristics of the materials being evaluated.

The principle that information on stability generated in any one of the three areas of the EC, Japan and the USA would be mutually acceptable in both of the other two areas has been established.

Further details of the specific requirements for sampling, statistical analysis, test requirements for particular dosage forms/packaging etc., may be found in the relevant national/regional guidelines.

Objective

The purpose of stability studies is to establish how the quality of a drug substance or drug product varies with time under the influence of a variety of environmental factors such as temperature, humidity and light, and enables recommended storage conditions, re-test periods and shelf lives to be established.

Scope

The guideline primarily addresses the information required in Registration Applications for new drug substances and products. Similar general principles apply to less stable materials when appropriate modifications will be necessary to cover the specific characteristics encountered. The guideline does not currently seek to cover the information required for abridged applications, variations, biotechnology/biological products, clinical trials applications etc.

The basis for the scientific principles covering derivation of the standardised temperature and humidity conditions recommended is given in Annex 1. The choice of the test conditions defined in this guideline is made from those stated in Annex 1 for the three areas of the EC, Japan and USA.

Glossary and Information

The following terms have been in general use and the following definitions are provided to facilitate interpretation of the guideline.

Accelerated Testing

Studies designed to increase the rate of chemical degradation or physical change of an active drug substance or drug product by using exaggerated storage conditions as part of the formal, definitive, storage programme. The test conditions are also used to provide comparative evidence in the short term of the equivalence of materials from various sources such as made by different manufacturers or processes or procedures or in different packagings, or where volumes or strengths of drug products are involved.

These data may also be used to assess longer term chemical effects at non-accelerated conditions and to evaluate the impact of short term excursions outside the label storage conditions such as might occur during shipping. Results from accelerated testing studies are not always predictive of physical changes.

Studies may be undertaken to identify the most sensitive dosage strength, container/closure system, and/or container size among various forms of the same drug product. For Japan the Long Term Testing could then be performed with only the selected least stable dosage strength, container/closure system, and/or container size. In this case other forms should be more stable and need therefore not be tested, thus offering an alternative to Matrixing and Bracketing to reduce the number of samples tested.

Active Substance: Active Principle: Drug Substance: Medicinal Substance

The unformulated drug substance which may be subsequently formulated with excipients to produce the drug product.

Bracketing

The design of a stability schedule so that at any time point only the samples on the extremes, for example of container size and/or dosage strengths, are tested. The design assumes that the stability of the intermediate condition samples are represented by those at the extremes.

Climatic Zones

The concept of dividing the world into four zones based on defining the prevalent annual climatic conditions (see Annex 1).

Drug Product: Finished Product: Dosage Form

A pharmaceutical product type, for example tablet, capsule, solution, cream etc that contains a drug ingredient generally, but not necessarily, in association with excipients.

Excipient

Anything other that the drug substance in the dosage form.

Expiry/Expiration Date

The date placed on the immediate container label of a drug product designating the time during which a batch of the product is expected to remain within specification if stored under defined conditions, and after which it must not be used.

Formal (Systematic) Studies

Formal studies are those undertaken to a pre-approval stability protocol which embraces storage conditions and testing periods as recommended by these guidelines.

Long Term (Real Time) Testing

Stability evaluation of the physical, chemical, biological and microbiological characteristics of a drug product and a drug substance, covering the expected duration of the shelf life and re-test period, which are claimed in the submission and will appear on the labelling.

Mass Balance: Material Balance

The process of adding together the assay value and levels of degradation products to see how closely these add up to 100 per cent of the initial value, with due consideration of the margin of analytical precision.

This concept is a useful scientific guide for evaluating data but it is only occasionally achievable in most circumstances. The focus may instead be on assuring the specificity of the assay, the completeness of the investigation of routes of degradation, and the use, if necessary, of identified degradants as indicators of the extent of degradation via particular mechanisms.

Matrixing

The statistical design of a stability schedule so that only a fraction of the total number of samples are tested at any specified sampling point. At a subsequent sampling point, different sets of samples of the total number would be tested. The design assumes that the stability of the samples tested represents the stability of all samples. The differences in the samples for the same drug product should be identified as, for example, covering different container/closure systems, different batches, different strengths, different sizes etc.

Matrixing can cover reduced testing when more than one variable is being evaluated. Thus the design of the matrix will be dictated by the factors needing to be covered and evaluated. This potential complexity precludes inclusion of specific details and examples, and it may be desirable to discuss design in advance with a regulatory body where this facility is available. In every case it is essential that all batches are tested initially and at the end of the long term testing.

Mean Kinetic Temperature

When establishing the mean value of the temperature the formula of J. D. Haynes (J. Parm.Sci.60, 927–929, 1971) can be used to calculate the mean kinetic temperature. It is higher than the arithmetic mean temperature and takes into account the Arrhenius equation from which Haynes derived his formula.

Pilot Plant Scale

The manufacture of either drug substance or drug product by a procedure fully representative of and simulating that to be applied on a full manufacturing scale.

For oral solid dosage forms this is generally taken to be at a minimum scale of one tenth that of full production or 100,000 dosing units for the drug product whichever is the larger. The alternative use of smaller scale batches in providing stability information needs to be justified.

Primary Stability Data

Data on the drug substance stored in the proposed packaging under storage conditions that support the proposed re-test date.

Data on the drug product stored in the proposed container-closure for marketing under storage conditions that support the proposed shelf life.

Re-Test Date

The date when samples of the drug substance should be re-examined to ensure that material is still suitable for use.

Re-Test Period

The period of time during which the drug substance can be considered to remain within the specification and therefore acceptable for use in the manufacture of a given drug product, provided that is has been stored under the defined conditions; after this period, the batch should be retested before use.

Shelf-life

The time interval that a drug product is expected to remain within the approved specification provided that it is stored under the conditions defined on the label in the proposed containers and closure. This may be regarded as equivalent to the Expiration Dating period.

Specification—Release

The combination of physical, chemical, biological and microbiological test requirements that determine a drug product is suitable for release at the time of its manufacture.

Specification—Check/Shelf-Life

The combination of physical, chemical, biological and microbiological test requirements that a drug substance must meet up to its re-test date or a drug product must meet throughout its shelf life.

Storage Conditions Tolerances

The acceptable variation in temperature and relative humidity of storage facilities.

For temperature the three month time weighted average fluctuations should be within ±2 °C.

For Relative Humidities the three month time weighted average fluctuations should be within ±5 per cent.

Stress Testing

The studies undertaken, primarily on the drug substance but also on the drug product, to elucidate intrinsic stability characteristics. Such testing is part of the development strategy and is normally carried out under more severe conditions than those used for accelerated tests.

Stress testing is conducted to provide data on forced decomposition products and decomposition mechanisms for the drug substance. The severe conditions that may be encountered during distribution can be covered by stress testing of definitive batches of drug substance and drug product.

These studies should establish the inherent stability characteristics of the molecule, such as the degradation pathways, and lead to identification of degradation products and hence support the suitability of the proposed analytical procedures. The detailed nature of the studies will depend on the individual drug substance and type of drug product.

This testing is likely to be carried out on a single batch of material and to include the effect of elevated temperatures, susceptibility to hydrolyse across a wide range of pH values in solution or suspension, oxidation and photolysis on the drug substance.

Results from these studies will form an integral part of the information provided to regulatory authorities.

Light testing should be an integral part of stress testing. [The standard conditions for light testing are still under discussion and will be distributed in a further ICH document].

It is recognised that some degradation pathways can be complex and that under forcing conditions decomposition products may be observed which are unlikely to be formed under accelerated or long term testing. This information may be useful in developing and validating suitable analytical methods, but it may not always be necessary to examine specifically for all degradation products, if is has been demonstrated that in practice these are not formed.

Supporting Stability Data

Data other than primary stability data, such as stability data on early synthetic route batches of drug substance, small scale batches of materials, investigational formulations not proposed for marketing, related formulations, product presented in containers other than those proposed for marketing, information regarding test results on containers, and other scientific rationale that support the analytical procedures, the proposed re-test period or shelf life and storage conditions.

Drug Substance

General

Information on the stability of the drug substance is an integral part of the systematic approach to stability evaluation. This can involve stressing the drug substance under a variety of conditions of temperature, humidity, exposure to light, together with testing in solution or suspension at a range of high and low pH values and evaluating the influence of oxygen. This stress testing helps to determine the intrinsic stability of the molecule by establishing degradation

pathways in order to identify the likely degradation products and to validate the stability indicating power of the analytical methods used.

Formal systematic studies will show that the drug substance will remain within specification during the re-test period if stored under recommended storage conditions.

Selection of Batches

Stability information from accelerated and long term testing is to be provided on at least three batches. The long term testing should cover 12 months duration on at least two of the batches at the time of submission.

The batches manufactured to a minimum of pilot plant scale should be by a synthetic route, or other appropriate method of manufacture, and procedure that simulate the final process to be used on a manufacturing scale. The overall quality of the batches of drug substance should be representative of the quality of material made on a manufacturing scale.

Data on laboratory scale batches may be provided to justify absence of 12 months definitive data on three pilot plant or larger scale batches. If not covered by the information provided in the Registration Application confirmatory stability information should be provided at a later stage.

Test Methods and Test Criteria

The testing should cover those features susceptible to change during storage and likely to influence quality, safety or efficacy. Validated stability-indicating testing methods must be applied. The need for the extent of replication will depend on the results of validation studies.

Specification

Limits of acceptability should be derived from all the available stability information. It may need to include specific limits for degradation products, the justification for which could be influenced by the level observed in material used in pre-clinical studies.

Storage Test Conditions

The length of the studies and the storage test conditions should be sufficient to cover storage, shipment and subsequent use. Application of the same storage conditions as applied to the drug product will facilitate comparative review and assessment. Other storage conditions are allowable if justified. In particular, temperature sensitive drug substances should be stored under an alternative, lower temperature condition which will then become the designated long term testing storage temperature. The six months accelerated testing should then be carried out at a temperature at least 15 °C above this designated long term storage temperature (together with the appropriate relative humidity conditions for that temperature). The designated long term testing conditions will be reflected in the labelling and re-test date.

Conditions		Minimum Time Period at Submission
Long term testing	25 °C ±2 °C/NLT [1] 60% RH ±5%	12 Months
Accelerated Testing	40 °C ±2 °C/75% RH ±5%	6 Months

[1] NLT = Not less than.

Should any significant change occur under the conditions used for accelerated testing it is strongly recommended that additional testing be carried out over at least a six month period at an intermediate condition (such as 30 °C ±2 °C/NLT 60 per cent RH ±5 per cent) providing a more severe thermal challenge than the designated long term testing condition, and that this information should be included in the Registration Application.

The long term testing will be continued for a sufficient period of time beyond 12 months to cover all appropriate re-test periods, and the further accumulated data can be submitted to the Authorities during the assessment period of the Registration Application.

Testing Frequency

Frequency of testing should be sufficient to establish the stability characteristics of the drug substance. Testing under the defined long term conditions will normally be every three months, over the first year, every six months over the second year and then annually. Reduced testing can be acceptable if justified, especially for stable substances.

Packaging/Containers

The containers to be used in the long term, real time stability evaluation should be the same as or simulate the actual packaging used for storage and distribution.

Evaluation

A systematic approach should be adopted in the presentation and evaluation of the stability information, which should cover as necessary physical, chemical, biological and microbiological test characteristics. Where applicable and meaningful, for example where there has been a significant change, formal statistical evaluation such as regression analysis may be applied. Any such evaluation should consider not only the assay but also the levels of degradation products and other appropriate attributes.

The drug substance must meet the requirements of the specification throughout its re-test period. Extrapolation may be acceptable where supported by accelerated and real time data. Accelerated data may be particularly useful in comparing different manufacturers, scales of manufacture, variables of manufacturing process and different batches to establish batch to batch variability before real time data are available.

Statements

A re-test period should be derived from the stability information.

Labelling

Based on the stability evaluation the drug substance may be assigned where suitable and appropriate to one of the following categories and labelled accordingly.

1. No specific storage precautions conditions necessary.
2. Store at up to 30 °C.
3. Store at up to 25 °C.
4. Store at 2 – 8 °C - refrigerate; do not freeze.
5. Store below 8 °C - refrigerate.
6. Store below -5 °C - freeze.
7. Store below -18 °C - deep freeze.

A storage temperature range may be used, and should specifically be stated where required in particular for drug substances that cannot tolerate freezing.

Reference to storage under ambient conditions or room temperature is unacceptable. Alternative presentations such as "Store below 25 °C" may be acceptable. General precautionary statements of "Protect from Light" and "Store in a Dry Place" may be included, but should not be used to cover drugs with stability problems.

Drug Product

General

The design of the stability programme for the finished drug product should be based on the knowledge of the behaviour and properties of the drug substance and the experience gained from the stability studies on the drug substance. The likely changes on storage and the rationale for the selection of product variables to include in the testing programme should be stated.

Selection of Batches

Stability information from accelerated and long term testing is to be provided on at least three batches of the same formulation proposed for marketing. The long term testing should cover at least 12 months duration on at least two of the batches at the time of submission. The manufacturing process to be used should meaningfully simulate that which would be applied to large scale batches for marketing. The process should provide product of the same quality intended for marketing, and meeting the same analytical specification as to be applied for release of material. Where possible, batches of the finished product should be manufactured using identifiably different batches of drug substance.

Data on laboratory scale batches may be provided to justify absence of 12 months definitive data on three pilot plant or larger scale batches. If not covered by the information provided in the Registration Application confirmatory stability information should be provided at a later stage on three early production batches

manufactured for marketing, normally the first three consecutive production batches.

When justified, data on associated formulations or packaging may be cross-referenced as supportive information if long term definitive data are not yet available.

Test Methods and Test Criteria

The testing should cover those features susceptible to change during storage and likely to influence quality, safety or efficacy. Analytical test methods should be fully validated and the assays should be stability indicating. The need for the extent of replication will depend on the results of validation studies.

The range of testing should cover not only chemical stability but also loss of preservative, physical properties and characteristics and organoleptic properties, where feasible.

Specifications

Limits of acceptance should relate to the release limits (where applicable), and be derived from consideration of all of the available stability information. The shelf life specification could allow acceptable and justified deviations from the release specification based on the stability evaluation and the changes observed on storage. It may need to include specific limits for degradation products, the justification for which could be influenced by the levels observed in material used in pre-clinical studies, where applicable. The justification for the limits proposed for certain other tests such as particle size or dissolution rate may require reference to the results observed for batch(es) used in bioavailability and/or clinical studies.

Storage Test Conditions

For drug products involving a new drug substance a minimum of 12 months stability information under the intended, long term, storage test condition should be provided, together with an assurance that testing will continue to cover the expected shelf life. Where available supporting stability data should be supplied.

Other storage conditions are allowable. In particular temperature sensitive drug products should be stored under an alternative lower temperature condition, which will then become the designated long term testing storage temperature. The six months accelerated testing should then be carried out at a temperature at least 15 °C above the designated long term storage temperature (together with the appropriate relative humidity conditions for that temperature). The designated long term testing conditions will be reflected in the labelling and expiration date.

Storage under conditions of high relative humidities applies particularly to solid dosage forms in semi-permeable packaging. For products such as solutions, suspensions etc., contained in packs designed to provide a permanent barrier to water loss, specific storage under conditions of high relative humidity is not necessary but the same range of temperatures should be applied. Low relative humidity can adversely affect products packed in semi-permeable containers (e.g. solutions in plastic bags, nose drops in small plastic containers etc) and consideration should be given to appropriate testing.

Conditions		Minimum Time Period at Submission
Long term testing	25 °C ±2oC/NLT[1] 60% RH ±5%	12 Months
Accelerated Testing	40 °C ±2oC/75% RH ±5%	6 Months

[1] NLT = Not less than.

For products which are intended to soften or melt at or below 37 °C (such as suppositories and ophthalmic ointments), or where significant changes occur under the conditions used for accelerated testing, it is strongly recommended that additional testing be carried out over at least a six month period at an intermediate condition (such as 30 °C ±2 °C/NLT 60 per cent RH ±5 per cent), thus providing a more severe thermal challenge than the designated long term testing condition. This information should be included in the Registration Application.

The long term testing will be continued for a sufficient period of time beyond 12 months to cover all appropriate re-test periods, and the further accumulated data can be submitted to the Authorities during the assessment period of the Registration Application.

The long term testing should cover the full expiration dating period and the labelling will reflect the results of the test under the conditions chosen for the long term testing.

Testing Frequency

Frequency of testing should be sufficient to establish the stability characteristics of the drug product. Testing will normally be every three months over the first year, every six months ove the second year and then annually. Reduced testing can be acceptable if justified, especially for stable products.

The use of matrixing or bracketing can be applied, if justified.

Packaging Materials

The testing should be carried out in the final packaging proposed for marketing or, when justified, in packaging that simulates the final one. Additional testing of unprotected drug product can form a useful part of the stress testing and pack evaluation, as can studies carried out in other related packaging materials in supporting the definitive packs(s).

Evaluation

A systematic approach should be adopted in the presentation and evaluation of the stability information, which should cover as necessary physical, chemical, biological, microbiological test characteristics, including particular properties of the dosage form (for example dissolution rate for oral dose forms). Where applicable and meaningful, for example where there has been a significant change, formal statistical evaluation such as regression analysis may be applied. Any such evaluation should consider not only the assay but also the levels of degradation products and other appropriate attributes. Where appropriate attention may be paid to reviewing the adequacy of the mass balance obtained.

Extrapolation of the shelf-life may be acceptable, where supported by accelerated and real time data. Accelerated data may be particularly useful in comparing different manufacturers, scales of manufacture, variables of manufacturing process and different batches to establish batch to batch variability before real time data are available.

An explanation should be provided if individual batches have a significantly different stability and degradation performance.

The stability of the drug product after reconstituting, either in specifically proposed mixtures or where a specific claim is made, should be addressed to provide appropriate information.

Statements/Labelling

Based on the stability evaluation the drug product may be assigned where suitable and appropriate to one of the following categories and labelled accordingly.

For Japan drug products shown to be stable need not necessarily carry storage statements. In the EC if there is evidence that batches of the stored product as packed for sale are stable at temperatures up to 30 °C, the product need bear no special temperature storage instructions. Within the USA all drug products require statements on storage conditions and so option (1) is not applicable.

1. No specific storage conditions necessary.
2. Store at up to 30 °C.
3. Store at up to 25 °C.
4. Store at 2 – 8 °C - refrigerate; do not freeze.
5. Store below 8 °C.
6. Store below -5 °C - freeze.
7. Store below -18 °C - deep freeze.

A storage temperature range may be used and should specifically be stated where required, in particular for drug products that cannot tolerate freezing.

Reference to storage under ambient conditions or room temperature is unacceptable. Alternative presentations such as "Store below 25 °C" may be acceptable. General precautionary statements of "Protect form Light" and "Store in a Dry Place" may be included, but should not be used to cover products with stability problems. Instead a packaging material should be used which offers the product suitable protection.

There should be direct linkage between the label statement and the demonstrated stability characteristics of the drug product.

Annex 1

Climatic Zones

For world-wide stability testing, the world is divided into four climatic zones (Futscher N. Schumacher P, Phar.Ind, 34, 479–483, 1972) for which the following storage conditions have been established on the basis of the values measured for a number of cities in the relevant climatic zone. Further information on the climatic data measured in the open and in storage rooms, and the derivation of the final combination of temperature and relative humidity covering the four climatic zones may be found in the following publications (Grimm W, Drugs made in Germany, 28, 196–202, 1985, and 29, 39–47, 1986). Climatic Zone II is established as being prevalent in covering EC, Japan and the USA.

Climatic Zone	Measured Data in the Open			Measured Data in Storage Room		
	[°C]	[% R.H]	[mbar]	[°C]	[% R.H]	[mbar]
I temperate	10.9	75	9.9	18.7	45	9.5
II Mediterranean Sub Tropical	17.0	70	13.5	21.1	54	13.1
III hot dry	24.4	39	11.5	26.0	54	18.0
IV hot humid	26.5	77	26.6	28.4	70	27.0

Climatic Zone	Calculated Data				Derived Data		
	<19 °C = 19 °C[1]						
	[°C]	[°C MKT][2]	[%]	[mbar]	[°C]	[%]	[mbar]
I temperate	20.0	20.0	42	9.9	21	45	11.2
II Mediterranean Sub Tropical	21.6	22.0	52	13.5	25	60	19.0
III hot dry	26.4	27.9	35	11.9	30	35	15.0
IV hot humid	26.7	27.4	76	26.6	30	70	30.0

[1] Drug products are stored in rooms. Consequently, 19 °C is used as the temperature for all months during which the temperatures measured are below 19 °C.
[2] Mean Kinetic Temperature

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Michael R. Taylor,

Deputy Commissioner for Policy.

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H.J. Res. 150/P.L. 103-14

Designating April 2, 1993, as "Education and Sharing Day, U.S.A.". (Apr. 12, 1993; 107 Stat. 45; 2 pages)

H.J. Res. 156/P.L. 103-15

Concerning the dedication of the United States Holocaust Memorial Museum. (Apr. 12, 1993; 107 Stat. 47; 2 pages)

S. 164/P.L. 103-16

To authorize the adjustment of the boundaries of the South Dakota portion of the Sioux Ranger District of Custer National Forest, and for other purposes. (Apr. 12, 1993; 107 Stat. 49; 1 page)

S. 252/P.L. 103-17

Idaho Land Exchange Act of 1993. (Apr. 12, 1993; 107 Stat. 50; 3 pages)

S. 662/P.L. 103-18

To amend title 38, United States Code, and title XIX of the Social Security Act to make technical corrections relating to the Veterans Health Care Act of 1992. (Apr. 12, 1993; 107 Stat. 53; 2 pages)

S.J. Res. 27/P.L. 103-19

Providing for the appointment of Hanna Holborn Gray as a citizen regent of the Board of Regents of the Smithsonian Institution. (Apr. 12, 1993; 107 Stat. 55; 1 page)

S.J. Res. 28/P.L. 103-20

Providing for the appointment of Barber B. Conable, Jr., as a citizen regent of the Board of Regents of the Smithsonian Institution. (Apr. 12, 1993; 107 Stat. 56; 1 page)

S.J. Res. 29/P.L. 103-21

Providing for the appointment of Wesley S. Williams, Jr. as a citizen regent of the Board of Regents of the Smithsonian Institution. (Apr. 12, 1993; 107 Stat. 57; 1 page)

S.J. Res. 53/P.L. 103-22

Designating March 1993 and March 1994 both as "Women's History Month". (Apr. 12, 1993; 107 Stat. 58; 2 pages)

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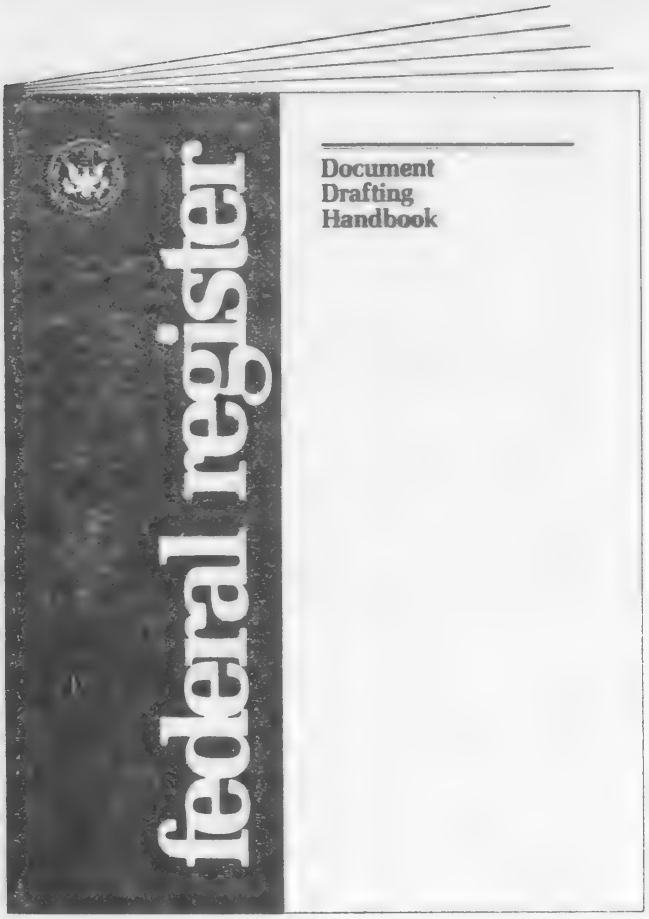

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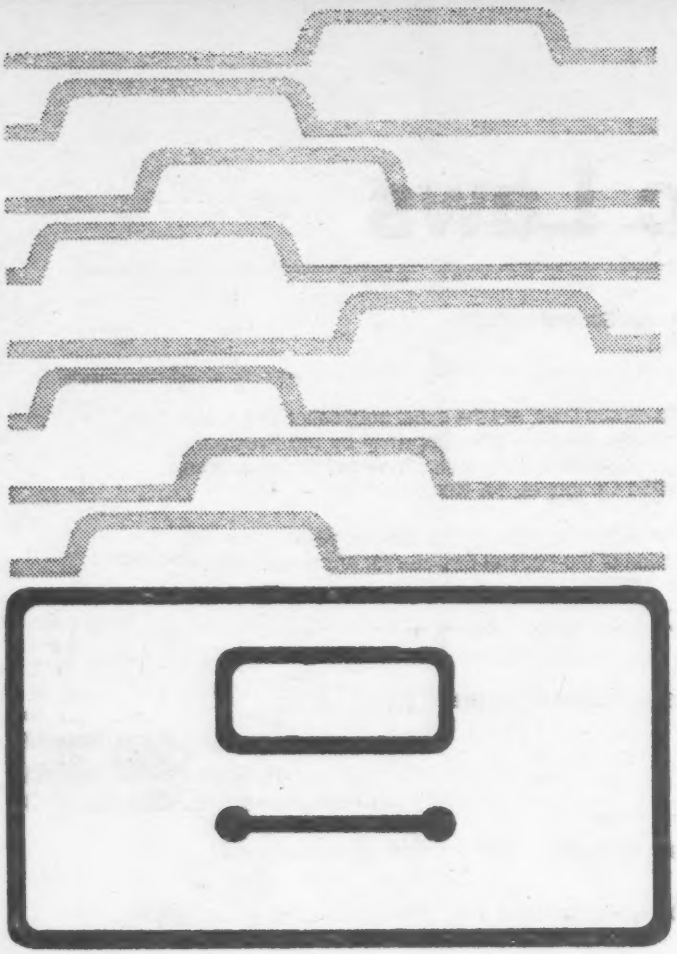

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